Pelvic Floor Muscle Biofeedback System

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Abstract

Combinations of incontinence, recurrent urinary tract infections (UTI) and constipation resulting from voiding dysfunctions afflict 20% to 30% of children in the United States. As these dysfunctions are driven by maladaptive muscular behavior, their treatments emphasize pelvic floor muscle retraining. With reliable commercial systems designed too broadly to fit our client's famously successful software, our project is to build an electromyography system that quantifies and outputs muscular exertion to a computer application which allows patients (and their nurses) to train and track progress. To do so, our system will incorporate electrodes placed on the skin with preamplifiers that send the amplified signal to a microcontroller. The microcontroller will send this information to a computer as a prompt user-interface command, such as a mouse-click or keyboard stroke. This command controls biofeedback games, which allow fast and easy training of urinary muscle groups.

Background

Medical and Biological

Voiding the bladder in a normal person is a complex series of events that involves a series of different muscle contractions. First, the urinary sphincter and the pelvic floor muscles (PFMs) must relax. Both of these sets of muscles surround the urethra (Figure 1). When they are contracting, they prevent the flow of urine. Once these muscles have relaxed, the smooth muscle that surrounds the bladder contracts and forces urine out through the urethra.[1]

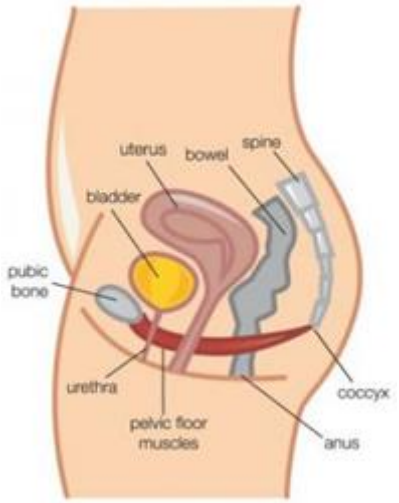

Figure 1. *The contraction of PFMs constricts the urethra to prevent voiding.*

Urinary incontinence can be caused by many different factors ranging from weak urinary sphincter muscles to excess pressure on the bladder. Contraction of the abs and pregnancy are just two factors that can increase pressure on the urinary bladder. In certain cases, increasing the strength of the PFMs can help reduce the severity of incontinence.[1]

The affliction of urinary incontinence (UI) encompasses many voiding issues that have to do with the loss of ability to control the bladder.[2] The most common voiding issue is nocturnal enuresis, or night time urination, which affects approximately 50% of children with UI.[3] This disorder and many others that accompany UI are normally treated by a wide variety of methods ranging from the simple behavioral techniques to more in depth surgical interventions. Some of the behavioral methods include a scheduled regimen of time for urination or simply a change in diet. Most of these rudimentary treatments are supplemented with medications that help calm bladder activity or target those with stress related UI. Surgical methods usually involve an implant or technique that helps strengthen or support the muscle associated with incontinence.[3] These methods, however, only lead to a success rate of around 20%, based on an interview with Dr. Patrick H. McKenna.

Biofeedback Games

To address this issue of a poor success rate, Dr. McKenna started to expand on an already widely used method called biofeedback in 1998.[4] Biofeedback involves the use of electrodes and an electromyography (EMG) system that captures information about one particular muscle group and its functionality.[5] The expansion involved the introduction a of video game that would use the biofeedback from both the abdominal muscles and PFMs.[4] This new training was warranted because of the known positive effects of biofeedback systems for curing incontinence; however, there was an inability to keep children committed and interested in the process.[5]

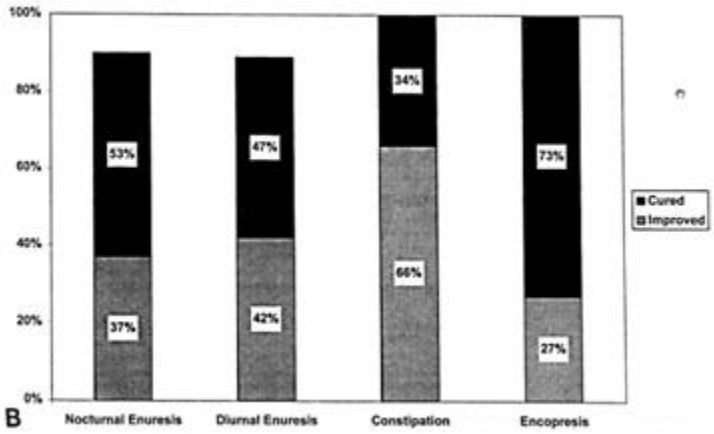

Figure 2. *The outcome of biofeedback games treatment at the end of the trial conducted in 1999 by McKenna et.al.3 (page 1059).*

To prove the effectiveness of the games on cure rate, there were two trials conducted by Dr. McKenna and his colleagues. The trials involved 41 and 160 children of varying ages that averaged out to be 7.2 and 8.5 years respectively.[4,5] The games worked by acquiring feedback that represented the flexion of the PFM and the relaxation of the abdominal muscle.[4] All of the children in the trials participated in approximately an hour of treatment per session that involved around 20 minutes of supervised gaming time.[5] The results of the study are shown in Figure 2. The 84% and 87% success rate in each trial proved conclusively that the method of using biofeedback paired with the video games is a viable option for the treatment of UI in children.[4,5]

Motivation

For almost 20 years, Dr. McKenna has had the best method of treatment for those who suffer from dysfunctional voiding of anyone in the world. Through his method of using biofeedback games in order to train his patients to strengthen and properly use their PFMs and abdominal muscles, he has been able to have an extremely high success rate. This level of success is well above that of other common methods, while at the same time being much less invasive and creating no potential harm to the patient. However, one negative about his system is that with a lack of updates throughout its existence, it has become extremely outdated. The

system still runs on the same hardware and software on which it was implemented almost 20 years ago, which causes it to function unreliably and unsustainably.

Often times, when the nurses try to ready the system for patient use, it simply does not work, which poses a major inconvenience for both the administrator and the patients. In addition, one of the major hardware components of the current setup overheats badly and burns itself out after a couple months of use. In the past, this created an annoyance as the device needed to be replaced, but the availability of spare devices made it so that this problem never posed a threat to the ability to implement this method of treatment. At the conclusion of this paper writing, our client's last remaining biofeedback device has failed. For this reason, updated hardware is essential in order to keep this amazing method of treatment available to the countless people who need it.

Problem Statement

As such, our task is to design a new product that can replace all of the current hardware components used in the system. This new piece of hardware must be able to perform all of the functions of the current hardware setup. More specifically, our device must be able to receive and process two EMG signals: one from the patient's abdominal region and another from the patient's pelvic floor. In addition, our hardware needs to be able to communicate with the current software and games that we have developed until that aspect of the system can be updated in the future. Our design also must work with the EMG sensing Kendall™ Neonatal Electrodes that the nurses are currently using, as they are ideal for enabling a secure and exact placement on the patients and function exactly as needed.

In addition to serving as a direct replacement for the current hardware, our new design aims to simplify the system by implementing a single container housing all of the hardware components and performing their tasks more efficiently.

As such, the new hardware will be much more user friendly, while also being much more reliable. Along with the aforementioned goals for our new product, there are various other requirements that our design must meet. Because of the large amount of patients currently on waiting lists for this treatment, our system must be able to handle five one-hour treatment sessions per day, five days per week. While doing so, it must maintain a safe and sustainable operating temperature in order to avoid many of the problems that the previous setup faced. In addition, it must have various safety measures in place so that there is no way the patient can be harmed by our product, even in the event of an unforeseen malfunction. Finally, the signal conversion to digital computer commands must be processed quickly with an Arduino microcontroller.[6]

Existing Devices

Many different devices that can receive and process multiple channels of EMG signals are already on the market. However, these products do not meet all of our necessary requirements, as they implement their own methods of biofeedback. One example is the MyoTrac™ system made by Thought Technology LTD., which gives the user feedback through a bright light bar and proportional tones.[7] In contrast, our hardware does not need to directly provide any kind of feedback to the patient. Instead, it must be able to send its data to a computer that is running Dr. McKenna's software, through which the patient will receive feedback in the form of a video game.

One specific example of a device that performs similar functions as our device is the Advancer Technologies Muscle Mouse. This device is a Bluetooth EMG system that can convert muscle activity into electrical signals that can be used to play online games. This device is nearly ideal for our client's situation except for some severe limitations. The Muscle Mouse can only have one input, so it would not be able to take inputs from both the pelvic floor and the abdomen. Since Dr. McKenna's system relies heavily on its ability to monitor both muscle groups, this is a key flaw with the Muscle Mouse. On top of this, it is not yet available for purchase. Without a set release date it will be of no use to Dr. McKenna.[8]

Current Design Status

After working on this project in previous semesters, our product was based heavily on an open source schematic from Advancer Technologies.[8,9] We are now trying to move from this device to a more easily commercialized one. Our goal is to have documentation and justification regarding all of the components in our final design. In terms of circuitry, it is necessary to determine an appropriate frequency response and gain of the device.

We analyzed various papers researching PFM and abdomen muscle activity during different tasks. In these papers, we were specifically interested in their EMG systems. Our goal when looking at the EMG specifications was to determine a standard frequency range that the researchers were interested in as well as the amplification level of EMG that they used. This will allow us to justify our circuitry decisions.

From the literature, we found that almost all of the researchers were using frequency windows of 10 to 500 Hz.[10,11] In these same papers, the overall circuit gain was 1000. We chose to use the same range of frequency response and gain that we found in our literature research. We made this decision primarily due to the fact that Auchincloss *et. al.* successfully showed that EMG activity, measured with a system with the same specifications, can be used as a biofeedback method to train PFMs in incontinent patients.[10] We also elected to use second order filters in our device to improve the gain roll off near corner frequencies. This will help ensure that our high-pass filter will reduce any DC offset and is further explained in the next section.

With our frequency response and gain chosen, our next step was to determine the number of steps that we wanted to spread our gain over. We decided to use a differential amplifier with a

gain of 10, a high-pass filter with a gain of 10, and a low-pass filter with a gain of 10 giving us a total gain of 1000. This was chosen to ensure that the high-pass filter would eliminate any DC offset. After the high-pass filter, the total gain will be 100 which is 40 dB. Second order filters have a 40 dB per decade roll off, so our high-pass filter with a cutoff frequency of 10 Hz will be able to remove any DC offset. As mentioned, these values are consistent with current commercialized EMGs.

After the input signals have been filtered, we pass the signal through a unity gain full-wave rectifier. We opted to do the signal processing in an analog manner to allow for more time improving the code that will run the game. We have also decided that since the system will be connected to the computer via USB for data transfer, it will be quite easy to use USB to power the device. We will use a DC/DC converter to get plus and minus power from the 5v USB input.

For our final decision in terms of circuitry, we have decided to implement a driven right leg circuit to improve the common mode rejection ratio of the EMG. While testing our preliminary circuit for gain and frequency response, we noticed significant 60 Hz noise. This noise affects the signal and can lower patient's ability to play the game by affecting the amplitude of the actual EMG signal.

We also needed to select a microcontroller to use to allow for the conversion of the EMG signal into game commands. We took several different microcontrollers into account and made a decision matrix to determine which microcontroller would suit us best. The decision matrix and the final microcontroller choice are discussed in the next section.

Major Design Decisions

With a well-established current design, many of the decisions we have had to make are specific components of the design described above. As a result, the following sections narrate the decision process for each of these components and our final conclusions. All of these conclusions are solidified as components of our first version.

Microcontroller Decision

First, various microcontrollers were considered for this new design. Specifically, the Arduino Micro, MSP430 Launchpad G2xx series, and PIC32 Pinguino were compared.[12,13,14] The Arduino Micro is an open source electronic prototyping platform that utilizes the ATmega32u4 microcontroller.[15] The Arduino developers provide a user friendly Arduino IDE that utilizes its own easy-to-learn language that is based on C. Additionally, there is an active community that utilizes the Arduino boards and frequently posts on the Arduino support forums. The MSP430 Launch Pad is a low cost, low power microcontroller development kit from Texas Instruments. It is very similar to the Arduino, having an IDE (Energia) created for it and also having a fairly active community behind it. Finally, PIC32 Pinguino is another open source microcontroller board developed by Olimex. The Pinguino boards are programmed in C. One

thing to note is that there is not nearly as much developer or community support provided for this microcontroller. A list of basic hardware specifications can be seen below in Table 1.

Specifications	Arduino Micro	MSP430 Launch Pad (G2xx)	PIC32 Pinguino
Input Voltage	7-12 V (+USB)	9-30 V (+USB)	9-30 V +(USB)
Clock Rate	16 MHz	up to 32 MHz	16 MHz
Memory (Flash/SRAM)	28KB/2.5KB	0.5-56KB/12B-4KB	32KB/8KB
Digital I/O Pins	20	up to 32	19
Analog In Pins	12	up to 32	9
ADC bits	10	16	10
Cost	$25.00	$9.99	$25.27

Table 1. *Hardware specifications for various microcontrollers. For the MSP430, the G2 series was used. All specifications are taken directly from the respective manufacturer documentation. For further specs, see references 12,13, and 14.*

The decision matrix in Table 2 was used to choose our microcontroller. The most important criteria were developer support and multi-channel capabilities, with both weighted at 25. Since the EMG signals may need to be both digitally filtered and then interpreted to output commands to the game, support to accomplish these two complicated tasks is crucial. Also, it is necessary to monitor two EMG signals simultaneously (PFMs and abdominal muscles), so it is extremely important that the chosen boards can simultaneously sample and interpret two EMG signals at a rate of 1,000 Hz. There may also be additional input and output demands on the board, such as a battery power level reader, battery level indicator, and detector for an improper power connection (i.e. connecting the board directly to wall power). As mentioned before, the Arduino and MSP430 both have a fairly active community and strong support system, while the PIC32 support/community is not as developed. Therefore, it was ranked lower in developer support. Both the Arduino Micro and the MSP430 microcontrollers have more pins than the Pic32 Pinguino, so they are both slightly higher in the multi-channel category. Hardware / software requirements is then weighted at 20. Powering these devices can all achieved by USB port power, and they each have flexible power input ranges. The MSP430 Launch Pad is rated slightly lower, as it is a fairly large board and takes up more space. Next is processing and analysis, which is weighted at 15. The MSP430 is rated the highest, as it has 16 bits of resolution and a successive approximation register analog-to-digital converter (SAR ADC), which significantly eases the processing load of sampling. Second is the PIC32, as it has significantly

more memory than the Arduino, although they both have the same clock rate. Finally, ease of use is weighted at 15, as it is important that there is flexibility in how the microcontroller can control the game and allow for a wide range of game inputs. The Arduino Micro is preloaded with computer key stroke and mouse function, so it is rated as a 5. Accomplishing this is significantly more complicated with the MSP430 and PIC32, so these were both rated lower.

As seen in Table 2, all of the microcontrollers scored fairly well, but ultimately the Arduino was chosen due to its ease of use, multichannel capabilities, and strong developer and community support.

Criteria	Weights	Arduino Micro	MSP430 Launch Pad (G2xx)	PIC32 Pinguino
Developer Support	25	5 (25)	5 (25)	4 (20)
Multi-Channel	25	5 (25)	5 (25)	4 (20)
Hardware / Software Requirements	20	4 (16)	3 (12)	4 (16)
Processing and Analysis	15	3 (9)	5 (15)	4 (12)
Ease of Use	15	5 (15)	3 (9)	4 (12)
Total Score	**100**	**90**	**86**	**80**

Table 2. *Decision matrix for microcontroller. Criteria were ranked, totaling to 100 points. Each option was scored from 1 to 5 for each criterion, and the scores were then scaled proportionately to the weight of each criterion. After summing the scores, the design with the greatest total score was determined to be the best option.*

Signal Processing Decision

There are two possible methods of processing the EMG signal: analog filtering and digital filtering. Analog filtering involves passing the pre-amplified EMG signal into a higher order active band pass filter that will further cascade into a full wave rectifier. The signal would then be low-pass filtered into a smooth curve and sampled by the microcontroller. Digital filtering still would utilize an active band pass filter to reduce noise and possible aliasing. The microcontroller would sample a non-rectified EMG at 1,000 Hz and then perform a moving window Fast Fourier Transform (FFT). This would result in frequency bins with resolution dependent on the length of the FFT window that could then be digitally filtered by simply ignoring undesired frequency bins.

The two most important criteria in the decision matrix are latency and processing load, each weighted at 35 (Table 3). Latency is of critical importance, as it is necessary that the system runs efficiently in order to offer immediate feedback to the patient. Since the analog processing would only be slightly limited by a final low-pass filter that smooths the signal, it is rated higher

than digital signal processing, which could have a significant delay depending on the length of the FFT window. This window could be fairly large (200 ms to 500 ms) depending on the frequency resolution necessary to accurately analyze the EMG signal. Significant delays caused by the system could confuse the patient and impede progress. Also, the processing load required by each method cannot be overly taxing of the microcontroller, as these devices have limitations. Analog filtering would have the slowest processing load possible, as this only requires microcontroller sampling and no additional processing. Digital filtering, however, would have to perform heavy computations throughout EMG capture. Next, signal integrity is weighted at 20. While it is important that we do not artificially tamper the signal, research has shown that some level of processing is critical to EMG interpretation.[10,16] Digital filtering would allow a more realistic signal to be captured, but again, increasing frequency resolution would be at the cost of latency. Analog filtering involves bandpass filtering and rectifying the EMG signal, so it does receive a poor score for signal integrity. Finally, cost is included, weighted at 10. Analog filtering would require the purchase of a few more inexpensive circuit components to build a rectifier, while digital filtering would not require these components.

As seen in Table 3, analog filtering scored much higher than digital filtering. We will be implementing this in our circuit as we proceed with the design process.

Criteria	Weights	Analog	Digital
Latency	35	4 (28)	2 (14)
Processing Load	35	5 (35)	2 (14)
Signal Integrity	20	2 (8)	4 (16)
Cost	10	4 (8)	5 (10)
Total Score	**100**	**79**	**54**

Table 3. *Decision matrix for signal processing method. Criteria were ranked, totaling to 100 points. Each option was scored from 1 to 5 for each criterion, and the scores were then scaled proportionately to the weight of each criterion. After summing the scores, the design with the greatest total score was determined to be the best option.*

Power Supply Decision

The third major design consideration for this project was the power supply for the device. As shown in the decision matrix of Table 4, the three power supplies considered were disposable batteries, rechargeable batteries, and USB power. Disposable batteries would consist of either a set of 1.5 V AA batteries or a pair of 9 V batteries, depending on the final circuit design and power requirements. This could result in a variety of voltages ranging from ±3 V to ±9 V. USB power would use the same cable that provides a data connection to the computer that the device is used with. Therefore, it would be a single +5 V rail with a current limit of 500 mA. The rechargeable batteries would consist of a battery pack with a charging circuit independent of the

USB data connection to the computer. This would allow for the device to be disconnected from a power outlet while in operation, while removing the need to replace batteries.

Criteria	Weights	Disposable Batteries	Rechargeable Batteries	USB Power
Safety	25	5 (25)	4 (20)	4 (20)
IRB Approval	20	5 (20)	3 (16)	4 (12)
Longevity	20	3 (12)	4 (16)	5 (20)
Ease of Use	15	2 (6)	3 (9)	5 (15)
Cost	10	3 (6)	1 (2)	5 (10)
Size	10	3 (6)	1 (2)	5 (10)
Total Score	**100**	**75**	**65**	**87**

Table 4. *Decision matrix for power supply. Criteria were ranked, totaling to 100 points. Each option was scored from 1 to 5 for each criterion, and the scores were then scaled proportionately to the weight of each criterion. After summing the scores, the design with the greatest total score was determined to be the best option.*

Out of the criteria used to determine the best power supply, patient safety was ranked the highest. Because the only source of energy in disposable batteries is the batteries themselves, they pose almost no risk to the patient, scoring the highest in safety. Rechargeable batteries and USB power would be directly or indirectly connected to a wall outlet, and with improper use or equipment failure, there is a small chance of harming the patient. The next most important criteria were the ease of obtaining IRB approval in a short amount of time so that human subject testing can proceed in a timely manner and the amount of time the device could be used at a time. The IRB has more stringent requirements for devices connected to wall power, so the disposable batteries again score the highest in that criterion. However, since the disposable batteries and rechargeable batteries have limited amounts of energy, USB power excels in longevity. Minor criteria considered were the ease of use of the device by the nurses, the cost of manufacture and long-term operation of the device, and the overall size of the device. USB power scored the highest in these criteria, as operation would entail simply connecting the cable when using the device and disconnecting it when finished. The nurses would not need to replace or recharge batteries. Additionally, USB power has the lowest overall cost, as the rechargeable battery pack is an expensive initial purchase, and the disposable batteries would incur a high long-term cost. The size of a device with USB power is also the smallest, as no additional room is needed for the batteries themselves, or a charging circuit.

As Table 4 shows, USB power scored the highest overall in the decision matrix. Therefore, we will implement it into the design as we proceed with the project.

Future Work

Prospective Timeline

A glance at the timeline below reveals our intentions with the design moving forward. As we continue to finish making some final decisions on hardware and software specifics, we look forward to beginning our testing and system validation. We anticipate testing in comparison to a modern industrial EMG specifically in electronic output categories such as frequency response, gain, and signal-to-noise ratios. Thereafter, we will look to affirm our design in a printed circuit board and pursue confirmation of safety from an Institutional Review Board (detailed below) before moving onto patient testing. The final thing we hope to achieve this semester is to continue our development of the software and video game.

Timeline - Biofeedback Games			FALL SEMESTER													
			SEPT			OCT				NOV				DEC		
			W3	W4	W5	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2
Deliverables	Owner	Duration														
Hardware		10 w														
Driven Right Leg	M & A	2 w		X	X											
Filter	S&S	2 w	X	X	Finished											
Arduino decision	M & A	2 w	X	X	Finished											
Differential Amp Testing	S&S				X											
EMG	All	2 w			X											
Ordering PCB	All	2 w														
Rework & order PCB	All															
TEST & VALIDATE		6 w														
Testing Protocol	Mike	2 w														
Signal Acq.	All	2 w														
EMG Confirm	All	2 w														
Patient Safety - IRB	All	2 w														
Testing PCB	All	1 w														
SOFTWARE AND GAME		3 w														
Ard. or Alt Prog	All	3 w														
Game Dev	All	3 w														
MEETINGS		13 w														
Advisor	All	All	9/16/2014	9/23/2014	9/30/2014	10/7/2014	10/14/2014	10/21/2014	10/28/2014	11/4/2014	11/11/2014	11/18/2014	11/25/2014	12/2/2014	12/9/2014	
Team	All	All	16 and 19	23 and 26	30 and 3	7 and 10	14 and 17	21 and 24	28 and 31	4 and 7	11 and 14	18 and 21	25 and 28	2 and 5	9 and 12	
Client	All	All														
PRESENT & PAPER		5 w														
Present	All	5 w			Finished									12/5/2014		
Paper	All	5 w				10/8/2014									12/10/2014	
Notebooks	All	All													12/10/2014	
Annotations			Greyed out boxes indicate the goal for the respecive projects													
			X-outed box indicates that the tasks is being worked on.													
			Tasks will be marked as finished with a bold finished.													

Figure 3. *Projected timeline for this semester.*

Testing

Since we are looking to meet commercial standards with our device, we will have to test various aspects of our device to ensure that they meet these standards. We will test our circuit part by part, and once pieces have been confirmed to work, they will be integrated to our final product. Our first round of testing will be making bode plots of our filters to guarantee that we have the correct bandwidth and gain. We will then check our rectifier with a sinusoidal input to ensure that it is indeed rectifying the signal. Since 60 Hz noise has been a problem that we have encountered, we will need to implement a driven right leg circuit. Once that has been implemented, we can perform a frequency spectrum and compare 60 Hz noise in each signal. Finally, we will test our output with the output of a commercially available device to see if our device is functioning properly.

Once the testing and validation of our hardware is complete and we have obtained approval from the IRB (detailed in a section below), extensive testing must take place in order to prove the effectiveness of our design in a clinical setting. The goal of this testing will be twofold. First, refinement of our software may be necessary in order to improve the training effectiveness of our system. Secondly, by recording data from an array of pediatric patients, we can bolster the strength of our submission for a patent. Additionally, human trial data that demonstrates successful application and muscular improvement would hugely benefit our application for FDA approval.

Overall, our testing is still an open process that is subject to change depending on the challenges that present themselves throughout our design process. Future research may result in a reconstruction of testing methods to assist the development and refinement of our biofeedback system.

Institutional Review Boards (IRB)

One of the major considerations for our design moving forward is the compatibility with Institutional Review Board (IRB) standards. By complying with the requirements for safety set by the IRB, our device will be proven to safely and effectively collect data in a clinical setting. Devices are formally given an "investigational device exemption" from this review process thereby allowing them to both be used and shipped for the purpose of conducting investigations without complying with other requirements of the Food, Drug and Cosmetic (FD&C) Act that applies to commercial products. [17]

In further detail, there is a variety of criteria that must be satisfied for approval from an IRB. Specifically, the standards require our risks to be minimized with sound design research. Additionally, we are required to prove anticipated benefits that offset the possibility for risks. Finally, we will need to inform all patients of the investigational stage of the device as well as that their data is recorded for clinical research analysis.

Food and Drug Administration (FDA)

In addition to the standards of safety from an IRB, testing our device also includes a variety of other precautionary procedures in order to implement commercially. Considered by the FDA as a Class II, Part 880, (General Hospital and Personal use Devices) Pediatric Medical Device, we anticipate our biofeedback system to be similar enough to current market electromyographs (predicate devices) to be exempt from high scrutiny 510(k) review process. [18] With this benefit, submitting our device to the FDA and handling appropriate fees with our client will allow a commercialization of our device.

Software Development

In order to fully commercialize our biofeedback system as our own intellectual property, we must fully develop accessory aspects of the design as well. In the future, we will look towards expanding the acquisition and user-interface of our current software.

With commercialization as one of the major goals for this device, a complete product should come with video game capabilities that make this method so successful. To accomplish this, we look to continue to program our own gaming software with an open licensing program, Gamemaker Professional. As of now, a preliminary game that exemplifies the combination of pelvic and abdominal contractions is show in the two figures. As one can observe, additional work will need to be done that will improve the user interface and educational benefit of the game. By improving the clarity of the gaming components, we anticipate natural improvements in the efficiency of retraining as patients spend more time on muscle development and less time on trying to understand the game.

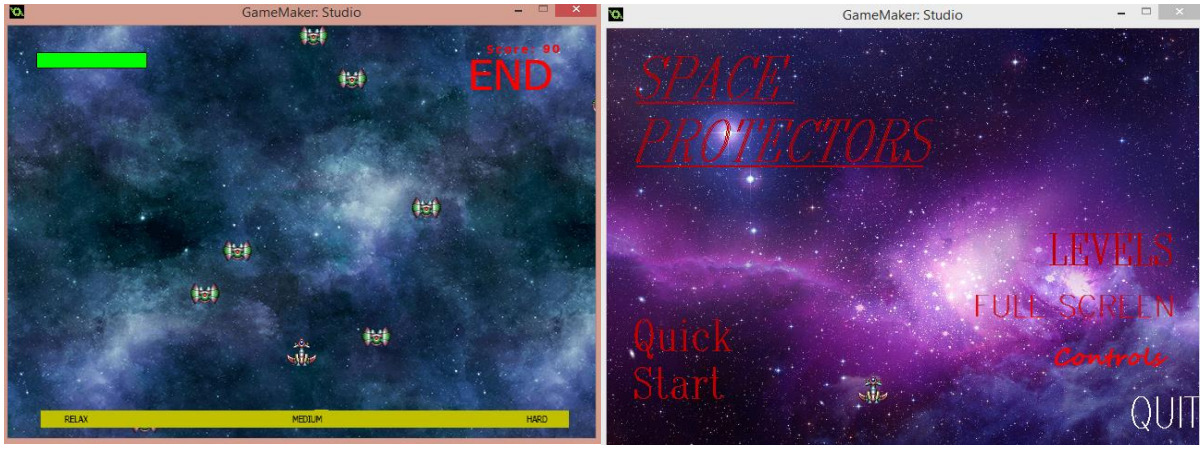

Figure 4. *Photo of current game design for the biofeedback system*

Conclusion

Current work on this project has focused largely on preparation and research into the details of commercializing and standardizing a medical device. From researching how we will acquire, filter, and analyze our signal, to drafting decision matrices for power supplies and microcontrollers, we have taken the time to ensure our device is up to modern clinical standards.

While this has been no small matter, we look forward to the remainder of the semester. During this time, we are excited to begin turning our design into a truly marketable and commercial product. Leading this desire will be applying for IRB approval and gathering data from patients to reinforce a presentation to the FDA and possibly patent submissions.

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Appendix A: Product Design Specifications

Pelvic Floor Muscle Biofeedback System
Project Design Specifications

October 8, 2014

Client: Dr. Patrick H. McKenna, MD, FACS, FAAP

Advisor: Dr. Amit Nimunkar

Team: Sam Lines (Leader)
Michael Simonson (Communicator)
Shawn Patel (BWIG)
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Function: Our Pelvic Floor Muscle Biofeedback Systems will analyze both the function and capability of muscles incorporated in the urinary process, including the lower abdomen and anal sphincter, by use of EMG sensors. This data will then be integrated with a software system that will allow feedback that is immediate and entertaining to the clients at hand.

Client Requirements:
Our client is looking for a system that:

- Maintains high standard of success rate
- Is updated and modernized
- Will be able to withstand a heavy schedule of use
- Held to safety standards of hospital equipment

Design Requirements:

1. Physical and Operational Characteristics

a. Performance requirements: This system will be used multiple times daily for the foreseeable future (1-3 years) the expectation is the software will run stably and consistently over that time.

b. Safety: Human factors set safety demands on our product that will not induce harm via muscle-stimulation or electrical malfunction

c. Accuracy and Reliability: Our system must output a low voltage to the computer software system with a range of error on the order of 100 mV. Outputs can be ~ 0 - 5 Volts.

d. Life In Service: Currently, patients' appointments are scheduled for 5 one-hour meetings per day, 5 days a week, for approximately the next year.

e. Shelf Life: No demands for product shelf life are currently anticipated due to the frequent use

f. Operating Environment: Hospital room setting, with no potential for exposure to conditions outside of normal indoors fluctuations in temperature and humidity. Temperatures will be at approximately 20 °C with a humidity of 30% to 50%.

g. Ergonomics: Sensors must be comfortable to apply and durable, maintain good contact throughout the potentially moving patient's exam

h. Size: Entire system must fit on 1 meter by 1 meter desktop. Sensors must be able to handle patients as low as 10 kg or as high as 150 kg.

i. Weight: Weight is only a concern for handling and transporting the device by the care providers. For this reason, the maximum weight of the device must not exceed 2 kg.

j. Materials: Materials should not be flammable under any hospital situation. Intuitively, we will search for the most cost/benefit effective products required to meet previously described demands.

k. Aesthetics, Appearance, and Finish: The software requires a modern feel and capability- an upgrade from 1990's DOS operating systems.

2. Production Characteristics

a. Quantity: We anticipate building at least one fully operational device and one backup device.

b. Target Product Cost: No real product cost or project budget has been established yet

3. Miscellaneous

a. Standards and Specifications: We will be looking at meeting human product testing requirements and hospital safety requirement

b. Patient Requirements: An exceptionally high (95%+) success rate will be demanded from our patients

c. Patent-Related Concerns: Business related potential for this project will continue to be research with a possibility for a project design patent and potential production

d. Competition: A variety of devices currently exist to output data in a numerical form, and are less accurate than the current generation of product. Our end product will be even more precise and integrate gaming software for play.