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**FIGURE # AND CAPTIONS FOR EACH FIGURE, MUST BE REFERENCED IN BODY OF TEXT (SEE DECISION MATRICES FOR EXAMPLES)**

FINAL EDITS DUE BY TUESDAY @ Meeting

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Pelvic Floor Muscle Biofeedback System

### *UW-Madison*

### *Department of Biomedical Engineering*

### *10/08/2014*

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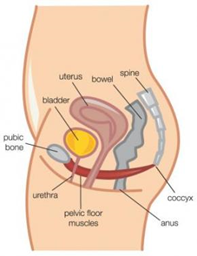
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# Abstract

Combinations of incontinence, recurrent urinary tract infections (UTI) and constipation resulting from voiding dysfunctions afflict 20% to 30% of children in the United States. Driven by maladaptive muscular behavior, treatment for these dysfunctions emphasizes pelvic floor muscle retraining. With reliable commercial systems designed too broadly to fit our clients 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

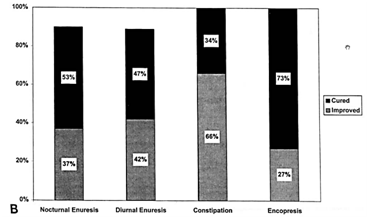
## Medical and Biological

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 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. 

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 pelvic floor can help reduce the severity of incontinence.

The affliction of urinary incontinence (UI) encompasses many voiding issues that have to do with the loss of ability to control the bladder.1 The most common voiding issue is nocturnal enuresis, or night time urination, which affects approximately 50% of children with UI.4 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 regiment 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.5 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 1998.2 Biofeedback involves the use of electrodes and an electromyography system that captures information about one particular muscle group and its functionality.3 The expansion involved the introduction a videogame that would use the biofeedback from both the abdominal and pelvic floor muscles.2 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.3

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.2,3 The games worked by acquiring feedback that represented a flexion of the pelvic floor and relaxation of the abdominal muscle.2 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.3 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.2,3

# 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 how to strengthen and properly use their pelvic floor 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 in addition to 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 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 until that aspect of the system can be updated in the future. As of now, this software runs on an old DOS operating system from the 1990s. Our design also must work with the EMG sensing KendallTM 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 perform 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 which our design must meet. Because of the large number 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 current setup is facing. 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.

As for the functionality of our hardware, it must be accurate and reliable. In order to properly interact with the Arduino calibration software, our code collects maximum (flexed) and minimum (relaxed) inputs. From here, we select 50% of the maximum as the accepted “contraction” limit, which in turn outputs a command to the computer.

# 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 tones7. 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 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 actually almost ideal for our 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 would be hard for Dr. McKenna to push his system until this product was available for purchase.8

# Current Design Status

After working on this project in previous semesters, our product was based heavily on an open source schematic from Advancer Technologies8. We are now trying to move from this device to a more standardized one. Our goal is to have documentation over 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 pelvic floor 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 the researchers were using frequency windows of 10Hz to 500Hz. [Auchincloss CC, Devreese A] In these same papers, we found them to use a gain of 1000. We choose to use the same values of frequency response and gain that we found in our literature research. This is mainly due to the fact that Auchincloss, Cindy C., and Linda Mclean, who were researching training of the pelvic floor muscle, found that EMG activity can be used as a biofeedback method to train pelvic floor muscles in incontinent patients. We also elected to use second order filters in our device to improve the roll off which will help ensure that our high-pass filter will reduce any DC offset. This will be 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 ten, a high pass filter with a gain of ten, and a low pass filter with a gain of ten. 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 40db per decade roll off, so our high pass filter with a cutoff frequency of 10Hz will be able to remove any DC offset.

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 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 right leg drive to improve the common mode rejection ratio of the emg. While testing our preliminary circuit for gain and frequency response, we have noticed significant 60Hz noise. This noise affects the signal and can lower patients 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 final choice are discussed in the next section.

# Major Design Decisions

design

## Microcontroller Decision

|  |  |  |  |
| --- | --- | --- | --- |
| 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 16 MHz | 80 MHz |
| Memory (Flash/SRAM) | 28KB/2.5KB | 0.5-56KB/12B-4KB | 256KB/32KB |
| Digital I/O Pins | 20 |  |  |
| Analog In Pins | 12 |  |  |
| Ease of Use |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 1.** 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.

Text

## Signal Processing Decision

signal

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **Weights** | **Analog** | **Digital** |
| Latency | 35 | 4 (28) | 1 (7) |
| Processing Load | 35 | 5 (35) | 2 (14) |
| Signal Integrity | 20 | 2 (8) | 4 (16) |
| Cost | 10 | 4 (8) | 5 (10) |
| **Total Score** | **100** | **83** | **47** |

**Table 2.** 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.

Text

## 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 3, the three power supplies we 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. The 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 3.** 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.

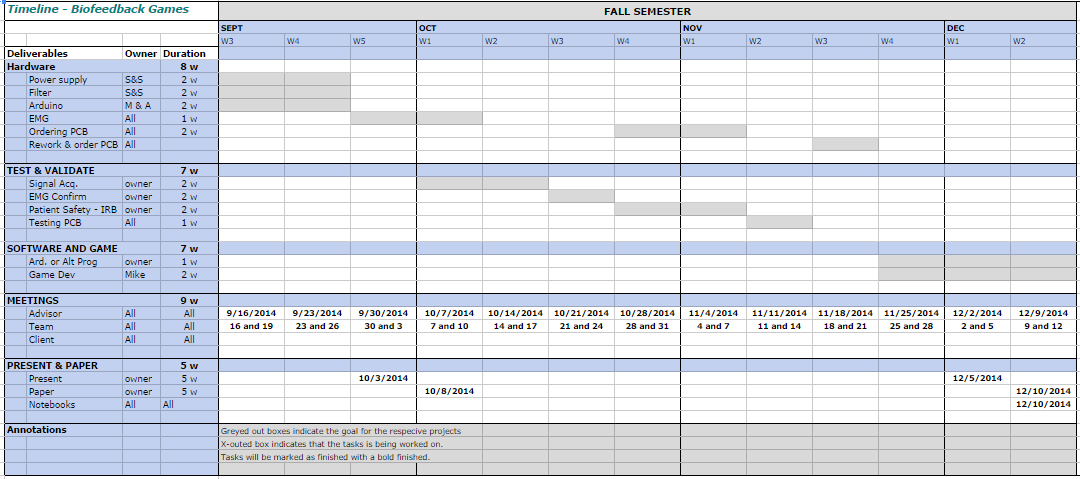
Out of the criteria used to determine the best power supply, patient safety was ranked the highest. Because the only source of energy in disposable batteries is the batteries themselves, they pose almost no risk to the patient, scoring the highest in safety. Rechargeable batteries and USB power would 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 3 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.

# Testing

# **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, 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 on software and video-game development. 

## Institutional Review Boards (IRB)

One of the major considerations for our design moving forward is the compatibility with Institutional Review Boards (IRB) standards. By complying with the requirements for safety set by the IRB, our device will be proved 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 both to 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. (CITATION)

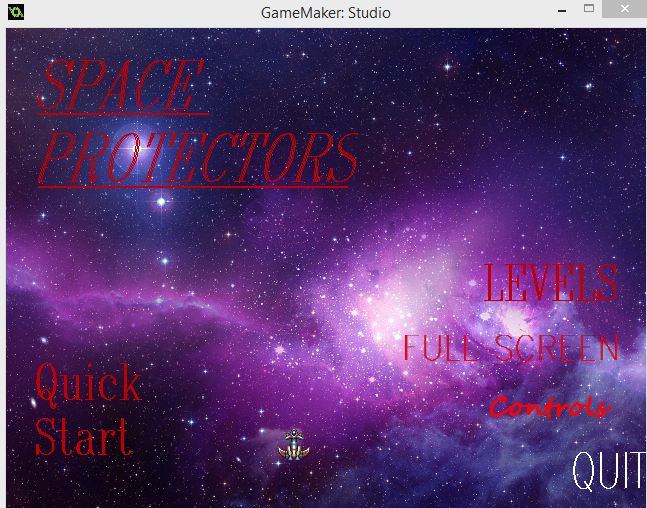
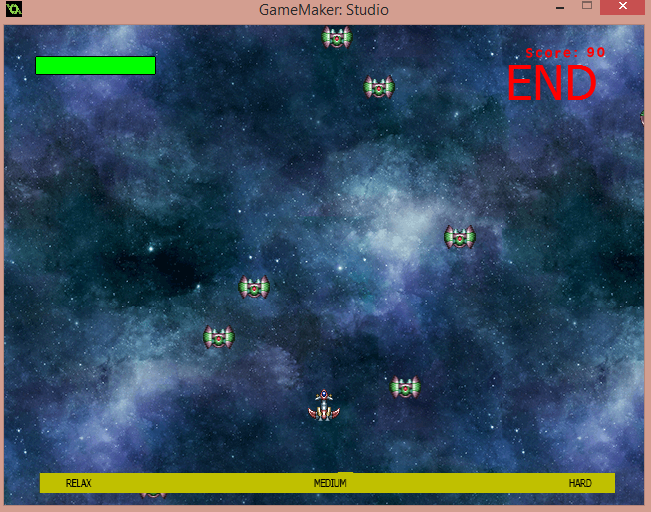
In further detail, there is a variety of criteria that must be satisfied for approval from an IRB. Specifically, the standards require our risks to be minimized with sound design research. Additionally, we are required to prove anticipated benefits that offset the possibility for risks. Finally, informing 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 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. (citation) 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 method, 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.

# Conclusion

So far work on this project has been largely 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 enforce a presentation to the FDA and possibly patent submissions.

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Devreese A, Staes F, Janssens L, Penninckx F, Vereecken R, De Weerdt W. (2007). Incontinent women have altered pelvic floor muscle contraction patterns. *The Journal of Urology. 178 (2).* 558-62.

“The electrodes were connected to a 6 channel EMG amplifier with a band pass filter of 10 to 500 Hz. Data were sampled by a 12 bit analog-to-digital converter at a rate of 1,000 samples per second, stored on a computer, full wave rectified and low pass filtered at 50 Hz to smooth the data”