Final Report

Seizure Monitor- Entrepreneur Project

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Abstract
Motivation for carrying out this project came from two separate arenas. First, the group was required by the BME department to complete a senior design project as part of their biomedical engineering undergraduate degree. Second, the team was inspired by the Entrepreneurial Senior Design Program to create a seizure monitor device based on its entrepreneurial market potential. The project involved designing and creating a seizure monitor which can be worn by patients. The monitor detects whether or not a seizure is occurring and then signals to an alarm which notifies the caregiver if a seizure is occurring. Finally, the data is transmitted via Bluetooth communication to a LabVIEW program that analyzes the seizure activity data and provides vital information to the patient’s physician. This device is essential in detecting serious seizures that otherwise may go undetected.

1. Introduction

1.1 Background (client and disability)

The Seizure Monitor Device does not have a particular client. However, the group has interviewed various doctors along with people who suffer seizures to get a better idea as to how to create the Seizure Monitor Device. The group felt it was important to both cater the project to the needs of patients who suffer from seizures and also to get the input of experts. Creating a project with advice from these individuals will hopefully lead to a better device for potential clients.

1.2 Purpose of the Project

The purpose of the Seizure Monitor Device is to detect a seizure, notify a caretaker, and provide seizure data to a physician for analysis. The device is to be worn by patients suffering from epilepsy (motor seizures only) to monitor seizures. Seizures which go unnoticed while a patient’s asleep can be extremely detrimental to one’s health, resulting in loss of consciousness, exhaustion, nausea, vomiting, and inadvertent injury. In the event of a seizure, the device will transmit a warning to signify to the caregiver that a seizure is in progress. The monitor has Bluetooth communication for a close proximity communication, flashing LEDs and a speaker for an auditory and visual warning system. This allows the caregiver to recognize an onset of a patient’s seizure. The size, mobility, and wireless capacity of the device are unusual and differ significantly from current seizure monitors which lie under the patient’s mattress.

1.3 Previous Work Done by Others

Currently, there has not been any previous Seizure Monitor Device created by UConn students. However, the idea of the Seizure Monitor Device came from a senior design project from Rochester Institute of Technology. The main goal of their project was to develop and validate a motion data collection system. This essentially would track when the person was having a seizure and record the time and duration of on a computer. This was communicated to the computer using an existing modified wireless communication system. The FSI evaluation kit included an accelerometer data collector, which was used as the motion monitoring device, and a
data concentrator module, which was used as the base device. Their data concentrator module was capable of receiving data from up to 16 accelerometer data collectors. Upon activation, the motion monitoring devices will continuously transmit motion data, via a ZigBee network, to the base unit. The base unit then transmits the data via an Ethernet (UDP) connection to a personal computer that will collect the data.

1.3.1 Products

There are a few products currently available that are similar to our proposed seizure monitor. The first one is the Medpage ST-2. The Medpage ST-2 is a monitor designed to detect and raise an alarm from a sleeping person experiencing regular muscular convulsions such as an epileptic seizure or convulsions caused by hypoglycemia in a diabetic person. The ST-2 monitor provides dual detection functionality, seizure monitoring and bed occupancy detection. A sensor is placed under the user’s mattress, bed or cot. During sleep movements from the patient are monitored by the ST-2 microprocessor. Prolonged irregular movements result in an alarm being generated by the monitor with a signal transmitted to the alarm pager or other alarm in use with the ST-2 monitor. The transmitter also has a call button and a socket that allows connection similar to a standard hospital nurse call switch. The transmitter also has some specialized easy operation switches for the physically disabled. Finally, it has built in tone alarms that can be set to produce a sound alarm when a bed seizure monitor has detected a seizure or the person leaving their bed.

Another product is the MP5 - Complete System - Bed Motion Alarm for convulsive movement such as Epilepsy Seizures. This system works by detecting shaking or jerking movements such as those encountered during convulsive seizures as well as sounds/noises. It will not detect mild seizures, and should not be used for people under 56lbs. However, if the mattress is thick, or the bed is large, the user would need to use two sensors to offer the same system features and functions. The system is set up by placing the sensors between the mattress and box spring. It is essential that the box spring be under the heaviest part of the user’s body. From there, the pagers are turned on and given to the caretakers and the sensitivity controls set. The bed monitor communicates with the wireless pagers up to a distance of approximately 328 feet.

Another product is the Emfit Nocturnal Tonic-Clonic Seizure Monitor. The Emfit Movement monitor consists of a flexible and durable bed sensor (L-4060SL), which is placed under the mattress, and a bed-side monitor (D-2090-2G). The Movement Monitor detects when a person has continuous quick-paced movements over a preset period of time and then triggers a notification. The system also notices light movements, thus making it equally suitable for small children. The control unit can be placed next to the bed or on the wall using the included fastening bracket. It is operated with 2 standard AA size 1.5 V batteries.

1.3.2 Patent Search Results

Implantable seizure monitor (United States Patent Application 20100210964) was a patent aimed at detecting seizure monitors. This is an implantable seizure monitor that can include at least one sensing electrode and an electronics module configured to detect record and/or log neurological events. For example, the electronics module can be configured to detect brainwaves indicative of seizures, such as, for example, epileptic seizures, and to create a log
indicating when such seizures occur. The implantable seizure monitor can include a cushioning member made of a soft material and configured to be implantable between the epidermis and cranium of a patient.

Another patent is the Brain Signal Telemetry and Seizure Prediction (Pub. No US 2008/0077039 A1). This patent involves an ambulatory intrinsic brain signal processor circuit which is coupled to many different electrodes placed on different regions of the brain. In conjunction with a digital multiplexer, the electrodes feed data wirelessly to and from a remote transceiver. There is a controller that allows the user to decide: which of the electrodes contribute data, the resolution of that data, and whether the data includes one or both of the neural action and local field potential data. Correct placement of the electrodes can help predict seizures.

1.4 Map for the Rest of the Report

The remainder of the report will explore the design for the project. The summary of the optimal design will include its purpose, subunits, constraints, and safety issues. The impact on engineering solutions, contributions of each team member, and the team’s lifelong learning will also be discussed.
2. Project Design

2.1 Optimal Design

2.1.1 Objective

Over three million Americans suffer from spontaneous seizures. Our device can significantly improve the lives of these patients in many ways. First and foremost, the device serves to revolutionize patient safety for those who suffer from epilepsy and other seizure disorders. When a patient begins to experience a motor seizure, the alarm system is activated and thus alerts the caregiver of the medical situation. Patients who suffer from seizures can lose consciousness, vomit, or severely injure themselves. By using the seizure monitor device, a caregiver will be notified of the seizure and can therefore help by providing the necessary medical assistance. Secondly, the device provides vital physiological information through specific measurements of seizure activity to the patient’s physician. The physician can learn more about the seizure’s duration, severity, frequency, etc. This information is vital in providing the correct medical treatment. Not only does the device offer enhanced safety and medical treatment for the patient, but it is small in size and aesthetically pleasing, which will be attractive to the consumer market. Patients will be excited about buying a device that won’t detract from their daily life. Current devices consist of mattress pads and thus make vacations and sleepovers nearly impossible.

The Seizure Monitor Device does not have a particular client. However, the group has interviewed various doctors along with people who suffer seizures to get a better idea as to how do go about creating the Seizure Monitor Device. The group felt it was important to both cater the project to the needs of patients who suffer from seizures and also to get the input of experts. Creating a project with advice from these individuals will hopefully lead to a better device for potential clients.

Seizures which go unnoticed while a patient’s asleep can be detrimental to the patient’s health, resulting in loss of consciousness, exhaustion, nausea, vomiting, and inadvertent injury [1]. In the event of a seizure, the device transmits a warning to signify to the caregiver that a seizure is in progress. The product is a small, wristwatch-like accessory that is worn 24 hours a day. The monitor catalogs the time, duration, and severity of a seizure for evaluation by one’s doctor. The monitor has Bluetooth communication for close proximity communication. It also boasts flashing LEDs and a speaker for an auditory and visual warning system, which allows the caregiver to recognize the onset of a patient’s seizure.

The general set up of the Seizure Monitor project is shown in Figure 1.
Figure 1. Project Flow Chart

The flow chart is organized to follow the path of the signal produced by the seizure. The patient’s movement is traced using an accelerometer, which produces analog signals in the x, y, and z directions. The accelerometer’s signals are processed by a microcontroller and sent to the alarm via Bluetooth. The signals are received by the alarm’s Bluetooth, which interprets the electrical signals from the accelerometer and determines whether the patient is having a seizure. If a seizure is occurring, an alarm sounds, and LEDs flash. In addition, the microcontroller relays information about the seizure to a LabVIEW program on a computer via Bluetooth. The LabVIEW program saves the seizure data so that it can be seen at a later time or analyzed by a doctor.
2.1.2 Subunits

2.1.2.a Watch

The first component of the seizure monitor is the watch, shown in Figure 2. The watch is composed of an accelerometer, a surface mount microcontroller, a surface mount Bluetooth, 3 volt camera battery, and a Velcro strap. The internal components of which are shown in Figure 11.

Figure 2. Interior of Watch
The wristwatch portion of the seizure monitor uses an accelerometer to measure the changes in motion on a 3-dimensional axis. The ATtiny24a microcontroller performs an A/D conversion, and a surface-mount Bluetooth module then transmits the seizure information to the alarm system. The data will be analyzed and will sound an alarm if a seizure is detected. The Multisim design for the watch is shown in figure 3 below.

![Figure 3. Watch Design in Multisim.](image)

### 2.1.2.b Accelerometer

An accelerometer, as shown in Figure 4, functions by measuring the magnitude and direction of acceleration relative to free-fall. The accelerometer weighs .35 grams so it doesn’t add significant weight to the device. By using a 3-axis accelerometer as opposed to a 2-axis accelerometer, the motion detection is more accurate.

![Figure 4. 3-Axis Surface-MountAccelerometer](image)
A decent amount of research has been done regarding accelerometers and their use to detect and analyze seizures. Research done at the Kempenhaeghe Epilepsy Center found that, “ACM [Accelerometry]-based detection of simple motor seizures is feasible” [2]. They conducted a study involving mentally retarded patients who suffered from epilepsy. Patients were monitored for a week and recordings of their seizures were taken via ACM, EEG, and video. The research group found that in seizures characterized by motor phenomena, the ACM signals showed clearly defined and recognizable patterns. Seizures are separated into three distinct phases: the aura, the tonic phase, and the clonic phase. Each phase is associated with a specific ACM pattern.

The tonic phase refers to the stage when the patient’s muscles tense up and extremities are either pushed completely outwards or pulled entirely inwards. The research team found that ACM data corresponding to the tonic phase appeared in a “block like” pattern. See Figure 5 for the complete data [2].

![Figure 5. ACM Data from Tonic Phase](image)

The clonic phase consists of rapid contraction and relaxation of the patient’s muscles resulting in convulsions. The signals on the ACM recordings showed higher frequencies and appeared in a “burst like” pattern [2], as shown in Figure 6.
The above information serves to support the technical analysis for the project. The LabVIEW program uses this data to detect seizures using an accelerometer.

2.1.2. Accelerometer Signal Filter

There were two options when considering a filter for the accelerometer signals. We wanted the x, y, and z-axis signals to be accurate and with minimal noise in order to easily interpret data in LabVIEW. The first option was to create our own system of filters using op-amps as low-pass or Butterworth filters. This option was quickly disliked because of space taken up in the PCB. The second option was to purchase an accelerometer breakout board, which comes equipped with necessary capacitors to filter the noise from the accelerometer. The breakout board chosen is small, and offers simple connections to each of the accelerometer’s pins.

2.1.2.d Bluetooth

The watch utilizes a surface mount Bluetooth, shown in Figure 7, to communicate with the alarm clock. A surface mount Bluetooth was chosen because it needs little power and is only 13.4mm x 25.8mm x 2mm. The WT41-A Bluetooth creates a communication system between the Bluetooth in the watch, the Bluetooth in the alarm, and an accompanying computer with LabVIEW software.
2.1.2.e Watch Battery

The watch will be powered by a CR123 lithium 3 volt camera battery. The battery is small enough to minimize space while still providing a substantial life of around 7 days. See the section on the realistic constraints for more information about the environmental factors and energy storage associated with the batteries.

2.1.2.f Water Resistance

The watch is water resistant. Its enclosure is sealed using a watertight adhesive. Water resistance refers to objects that can be splashed but not fully emerged by water. The user can go out in the rain, wash dishes, or take a shower with the water resistant watch. The water resistant watch allows for most daily uses and is significantly more practical to build.

2.1.2.g Strap

The watch has a Velcro strap to attach the watch to the user’s wrist. Velcro was chosen because it is water proof, durable, and makes it so the watch can be used with any sized wrist. Velcro is also easy to take off.
2.1.2.h Watch Microcontroller

The microcontroller chosen for the watch was the ATtiny24A-SSU, which can be seen in figure 10. The group chose this microcontroller because it is a small surface mount unit, runs at a speed grade of 0-10 MHz at 2.7 – 5.5 volts, and draws minimal power. In addition, it has full Bluetooth connection capabilities, with additional input ports for the accelerometer inputs.

2.1.2.i Watch PCB

The watch contains a PCB to organize the circuitry in the watch. The circuit was first created in Multisim, and converted to a PCB using Ultiboard. The Gerber files from the Ultiboard design was then shipped to 4PCB.com for production. The completed Ultiboard schematic for the watch can be seen in figure 11.
2.1.2.j Connection to the System

The wristwatch-like seizure monitor analyzes the patient’s seizure activity and the alarm system detects seizure occurrence. If the accelerometer produces the signals of a seizure, the alarm system will notify a caregiver using speakers and lights for both audio and visual stimulation so that no seizure goes unnoticed. The components of the alarm system are carefully explained in the section 2.1.3.

2.1.3.a Alarm Clock

The alarm portion of the project, as seen in Figure 1, features a speaker and two LED lights. The LED lights will alternate flashing to increase awareness to the caregiver. The alarm has a toggle switch to turn the alarm clock on and off. Two batteries are used in the alarm: one 9-volt and one 3-volt camera battery. The 9-volt battery’s voltage is regulated to 3.3 volts using a simple voltage regulating system, which powers the alarm’s microcontroller, LEDs, and speaker. The 3-volt lithium camera battery only powers the Bluetooth, which reduces the need for a second voltage regulating system, and a second large 9-volt battery. The shape of the alarm is a rectangular box, which is simple and space efficient. It also permits ease of portability as it can be placed on any flat surface.

Below shows the internal components of the alarm system:
Figure 12. Internal View of the Alarm System.
The alarm PCB contains a Bluetooth module, microcontroller, voltage regulator, and connections for LEDs, a speaker, and battery power. The Bluetooth in the alarm system is designed to receive raw data from the seizure monitor for processing by the microcontroller. The filtered data is then to be sent to a computer or mobile device equipped with LabVIEW, where the data is analyzed and properties of the seizure such as time, duration, and intensity are cataloged. The Bluetooth and microcontroller in the alarm utilize surface mount technology, which reduces space and power consumption. The other PCB components are also small in size to reduce space. The input from the accelerometer is in analog form, thus the alarm’s microcontroller is programmed as an A/D converter, and multiplexer so that the signal can be analyzed by LabVIEW. The Multisim design of the alarm system is shown below in figure 13.

2.1.3.b Alarm Microcontroller

The alarm uses an ATmega644PA-AU microcontroller as seen in figure 14. This is a surface mount microcontroller, which reduces size, weight, and power consumption, while still permitting the processing speed and memory capabilities needed. It has 44 pins, which allows for more than enough I/O pins for the LED connection, a speaker, and the Bluetooth connections. The mega was chosen mainly because Adam Markman had experience programming it in a class, and we wanted to work with something familiar.
2.1.3.c Alarm Voltage Regulator

The 9 volt battery was chosen for is relatively small size, with ample power. Using the 9 volt battery opposed to two AA (1.5 volt) batteries made the design simpler, and it also permits ease in changing batteries because the user only needs to swap one battery instead of two. The 9 volts of power however needed to be brought down to around 3 volts in order to power the circuit components; the microcontroller, Bluetooth, LEDs and speaker each operate with a 3 volt supply. A MCP1702 linear voltage regulator was chosen, with a 3.3 volt output and up to 13.2 volt input. Using two 1µF capacitors at the input and output of the voltage regulator, the 9 volt battery’s voltage was successfully reduced to 3.3 volts, which is ideal for our system. The voltage regulator as it appears on the alarm PCB is seen in figure 15.

2.1.3.d Alarm Visual and Auditory Alert System

The alarm uses two red LED lights and a speaker to alert the patient’s caregiver, which is shown in figures 16 and 17 respectively. The visual and audio stimulus increases the awareness that a seizure is in progress. The speaker was taken from a “jWIN JX-M20 PLL Digital Tuning AM/FM Radio.” The radio was cheap to purchase, and also provided an enclosure for the speaker so that it could easily be implanted into the alarm enclosure.
2.1.3.d Alarm PCB

The alarm contains a PCB board, as shown in figure 18, to organize the circuitry in the alarm. The circuit was first created in Multisim, and converted to a PCB using Ultiboard. The gerber files from the Ultiboard design was then shipped to 4PCB.com for production.

Figure 18. Alarm PCB Design from Ultiboard.

2.1.3.e Alarm Enclosure

The alarm enclosure is a Serpac plastic enclosure, custom modified to suit our design. The plastic is durable and the shape is ideal for an alarm because it can lay on a flat surface without any stability issues. We drilled two holes for the LEDs, such that only the lens of the
LED is exposed to the environment. This reduces the chance of any foreign objects entering the alarm, and allows the rest of the LED to easily adhere to the underside of the casing. Another hole was drilled so that the toggle switch can protrude through, and a hole was also drilled for the speaker. The speaker hole was intentionally drilled at a radius smaller than the radius of the actual speaker. The speaker attaches to the underside of the alarm casing, and with the hole being smaller, this allows there to be a substantial bond between the plastic and the rim of the speaker. On the outside of the speaker hole, we created a plastic covering larger than the hole, with perforations so that the sound can escape successfully. This piece was glued to the outside of the plastic and it will help protect the speaker from outside debris.

2.1.3.f Testing Procedure

To test the watch portion of the seizure monitor a protoboard was tested with the accelerometer in place. Protoboard is useful in testing circuits because they don’t require soldering, and components are easily moveable [5]. An example of a common protoboard is seen in Figure 19.

![Figure 19. PB-103 Common Protoboard.](image)

Using a power supply and oscilloscope, as seen in figure 20, a voltage was applied to check that there were no errors in the circuit and that all elements were functioning as desired. Simple tests were conducted to see what kinds of ACM readings are recorded based on different motions. These motions could include opening a door, performing a jumping jack, and waving to a person. ACM data was compared to daily activity to examine what types of patterns can be expected from certain activities.
After the signal was found to be powerful and clear enough, the LabVIEW code further breaks down the signal and outputs the necessary seizure characteristics such as the time of the seizure, its duration, and its intensity.

2.1.3.g Programming

The group created the alarm clock and watch on a breadboard first to debug the code. The microcontroller chosen for the alarm clock was the ATmega644PA and the watch used the ATtiny24A. The AVR series microcontrollers were chosen because of their ease of use and because Markman was taking a microcontroller class that involved coding AVR microcontrollers.

To program the microcontroller, an AVRISP MKII Programmer was used because it can program both the ATtiny24A and the ATmega644pa. Moreover, the programmer is compatible with AVR Studio, which was used to code the microcontrollers. This program was able to tell us if the programmer was connected properly to the microcontroller and if it was not, it would provide troubleshooting advice to solve the issue.

The first objective was to establish Bluetooth communication between the alarm clock and a PC with HyperTerminal. The goal was to simply send the characters ‘ABAB’ from the alarm clock to HyperTerminal via Bluetooth. This was successful when using USART communication to establish this connection using a baud rate of 9600, 8 data bits, and 1 stop bit. Also, the UBBR value was 51, which was obtained from the data sheet.

An ADXL335 accelerometer was then hooked up to the alarm clock to see if the accelerations being outputted from the accelerometer could be displayed on HyperTerminal. This was done by using the ADC on the ATmega644PA to read the x, y, and z axis of the accelerometer. Once this was done, the ADC equation $\text{ADC} = \text{Vin} \times 1025/\text{Vref}$ was used to find $\text{Vin}$ ($\text{Vref} = 5\text{V}$). Once $\text{Vin}$ was found, modulus arithmetic was used to output $\text{Vin}$ to two decimal points. USART functions were then used to output the acceleration data to HyperTerminal via Bluetooth and display the x, y, and z axis accelerations. The data was able to flow as a 3-column
array where each column referred to an x, y, or z-axis from the accelerometer. The base value for each axis is 1.5g, and upon movement of the accelerometer, this value will increase or decrease depending on the direction of movement. An example of this data flow is shown in figure 21.

| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
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| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |
| 1.50 | 1.50 | 1.50 |

Figure 21. Accelerometer Data Flow in Hyperterminal.

The speaker was coded in the alarm clock by attaching a speaker to OCR0B of the ATMEGA644PA of the alarm clock; OCR0B is the output of the Pulse Width Modulation (PWM) signal. A PWM can be thought of as an analog output that is produced by the microcontroller. Since the speaker works by using an analog voltage source, the PWM could be used to power the speaker. To do this, an array was created to mimic a sine wave. A PWM was then created that would mimic the sine wave and thus the speaker would sound.

Lastly, LEDs were able to flash by using a timer overflow. A counter was created such that when the count inside of the timer overflow would get to a certain value, the LED would turn on/off. Thus, to the human eye it appears that the LED is flashing because it is happening so quickly.

The overall coding and troubleshooting method that was used can be seen in figure 22.

Figure 22. The Cycle of Programming a Microcontroller Using MPLAB.
2.1.4 LabVIEW

The LabVIEW program takes the Bluetooth signal relaying the information from the microcontroller, and displays it in a form similar to figure 21. The overall idea of the LabVIEW code is to receive the data and store that into an n x 1 array. The LabVIEW program in the future, will concatenate some of the data coming from the microcontroller so that each line will display the data of the seizure, the time, the duration of the seizure, and the degree of the seizure ranging from mild, medium, and severe seizure. LabVIEW has built in features that allow for it to easily communicate with a Bluetooth device. This information can then be sent to a doctor so they can observe the data and keep tab on the patient’s seizures.

LabVIEW has many debugging tools that make it so the code can run correctly. LabVIEW uses data flow so that the group is able to use highlight execution to follow data and see what happens to it when it goes from one point to another. Moreover, the group can set up outputs at different points of the code to track how it is changing and to ensure the program is working correctly.

The LabVIEW program includes a feature that calls a phone number and sends an email to be input by the caregiver, in order to notify someone in the event of a seizure. The phone number and email address can be a parent, caregiver, or other emergency contact. Before using the device, the user will input this number and email address into the LabVIEW program, and they can be changed in the same manner. An example of the email block diagram is shown in figure 23.

![LabVIEW Block Diagram of Emergency Email Contact](image)

Figure 23. LabVIEW Block Diagram of Emergency Email Contact.
2.2 Prototype

2.2.1 Watch

The final watch prototype is shown below in figure 24.

![Final Watch Prototype](image)

The watch encasing was created from a soft plastic material found in the machine shop. It was hollowed out using the milling machine with set dimensions for a perfect cut. Four drill holes with thread were also made in each corner. The clear top is made of a harder plastic, also found as scrap plastic in the machine shop. It uses 4 small screws to hold it in place. This allows for easy removal of the top in order to change the battery. The Velcro strap was glued to the encasing using a strong-hold crazy glue, and reinforced with using a hot-glue gun. The final prototype is larger than expected, but this is only because of limited resources in the machine shop. For use in the future, a premade case will be purchased from a manufacturing company.
2.2.2 Alarm

The final alarm prototype came out as expected. The PCB, batteries, speaker, and LED lights fit nicely into the purchased SERPAC enclosure. Two holes were drilled for the LED lights, but the lights are connected to square-centimeter housing, so the plastic was cut away around the holes. This allowed the LED lights to be more exposed, yet not poking out past the plastic top, to ensure that they wouldn’t be broken if the alarm was dropped. Another hole was cut for the toggle switch, and the switch fits nicely into it, using a washer and nut outside the casing to ensure no movement. The speaker hole was drilled so that the diameter was smaller than that of the actual speaker. This allows for the speakers circumference to be glued to the bottom side of the enclosure’s top, while still providing enough space for sound to travel. We wanted the speaker to be protected so we fabricated a shield that was glued to the topside, which has small perforations spaced evenly so that sound can travel through the shield. The enclosure uses four small screws, screwed in from the bottom, to hold it together. Again, this allows the user easy access to the batteries when they need to be changed. The alarm has a flat bottom surface for easy placement anywhere in a household or healthcare facility.

The outside and inside views of the alarm prototype are shown in figures 25 and 26.

Figure 25. Outer View of Final Alarm Prototype.
The final LabVIEW code prototype consists in three parts. One part is the code which allows the user to input a telephone number so that that number will be sent a text message in the event of a seizure. The second part, as seen in figure 27, is the code which allows the user to input an email address so that the caregiver can receive an email when a seizure is detected. The third portion of the LabVIEW prototype is the portion which connects the Bluetooth from the alarm to a Bluetooth dongle on the computer, and accepts data transmission.

These three portions of the LabVIEW will be combined, including a portion of code that needs to be added so that the seizure data can be broken down into intensity, duration, and frequency. This couldn’t be done in our timeframe because the seizure data from the accelerometer wasn’t able to be sent to the computer because the code to connect the watch to the alarm to the computer wasn’t completed. This is one of the main additions that a future senior design group will complete upon this becoming a continuation project.
3. Realistic Constraints

3.1 Economic Constraints

The main economic constraint pertaining to the seizure monitor design is the budget. Dr. Bennett from the Mechanical Engineering Department allotted our team a maximum of $5,000 to spend. The total amount of spending as of April 17\textsuperscript{th}, 2011 totaled to $1068. Clearly the team was able to stay within budget. The cost to mass-produce the seizure monitor and alarm system will be much less than the cost to design and build the prototype. Existing products range from a low of $330 to a high of over a thousand dollars. Our product will be competitively priced so that we gain market share, and this analysis was done in the business plan. The seizure monitor and alarm design is unlike anything on the market so the provided budget was the main economic constraint to our design project.

3.2 Environmental Constraints

The seizure monitor will be powered with two 3 Volt lithium camera batteries and one 9 Volt battery. This contributes to a prolonged life on the watch (of 7 days) while maintaining a relatively light weight. Disposal of batteries is an environmental constraint, as it is detrimental to the environment if batteries aren’t disposed of properly.

The system utilizes Bluetooth wireless communication to transmit seizure information, such as the time of a seizure, its intensity, and its duration. This capability takes away the need for multiple hospital visits because an epileptic patient’s doctor can monitor the seizures from
his/her office. The reduced hospital visits result in a decreased transportation cost and thus a decrease in one’s carbon footprint.

Another environmental constraint pertaining to our design is the weather. The seizure monitor will not function if exposed to heavy rain or snow. Adhering to the weather constraints greatly increases patient safety and accuracy in analysis of the seizure data. The chosen inner components have temperature ranges of -35 to 55 degrees Celsius, and thus the device should not be used in temperatures outside of this range.

### 3.3 Sustainability Constraints

The seizure monitor and alarm system is designed for a long life. Our design eliminates the risk of rust, wear-and-tear, and temperature changes that could result in defects such as the swelling of components.

The Velcro strap on the seizure monitor allows the user to adjust the size of the wristband according to the growing size of his/her wrist. This further increases the life of the monitor because it will be able to be used throughout the user’s lifetime, providing no other malfunctions.

One of the most important constraints related to sustainability is the replacement of batteries. Both the watch and the alarm have a battery life of 7 days and thus batteries should be replaced each week.

Further consideration as to the life of the product and its components needs to be examined because when on the market, it is important to maintain repeat-buying. If the components last too long, there will be little room for additional profit apart from the initial purchase. For now, and for all practical purposes, the design values the sustainability of the components.

### 3.4 Manufacturability Constraints

The seizure monitor and alarm system contains parts that are currently mass produced such as microcontrollers, Bluetooth modules, accelerometers, capacitors, LEDs, etc. The speaker for the alarm is taken from an existing product. With the microcontroller code, LabVIEW code, and appropriate PCB schematics, large-scale manufacturing of the seizure monitor and alarm system is possible. The parts that make up the design are also cheap when purchased in bulk, and this would further reduce the price of mass-producing the seizure monitor.

### 3.5 Health & Safety Constraints

When dealing with an alarm system, one must ensure that the alarm operates proficiently and without failure. The safety of the epileptic patient is at risk when a seizure occurs, and the seizure monitor is designed such that no seizure goes unnoticed. The alarm is designed with speakers and flashing LEDs for audio and visual stimulus. This will increase the caregiver’s awareness that the patient is experiencing a seizure and allow him/her to assist the patient throughout the seizure and assist in the patient’s recovery. The device also implements a text message service which sends a message to the caregiver’s phone when the patient is experiencing a seizure. The LabVIEW program will also be programmed accurately, and will take the filtered signal from the alarm and display information pertaining to the seizures time of occurrence, its intensity, and duration. This information will be processed and displayed to a
doctor so that appropriate measures can be taken. If for instance the occurrence of a patient’s seizures occur during certain times, or other trends appear, precautions like the dosage of medication, or the patient’s surroundings during seizures can be taken.

The watch is designed such that it will not inflict any harm if a seizure occurs. There are no sharp edges, and it is lightweight to reduce possible blows to the body during a seizure. The Velcro wrist strap allows the user to customize its size, and thus reduce the risk of cutting off one’s circulation.

3.6 Social Constraints

The design of the seizure monitor is based on functionality rather than an aesthetically pleasing appearance. That being said, patients will not be hesitant to wear our device based on its simplistic appearance and lightweight characteristics.

4. Safety Issues

There are a few safety issues associated with the Seizure monitor. The first involves the watch. The watch may not function properly in very wet conditions such as heavy rain. A malfunction could result in an incorrect reading or no reading at all. Moreover, the watch should never overheat and burn the patient’s wrist. If the watch begins to heat up, a problem is likely occurring within the circuit and the user must remove the watch. The watch must also be comfortable to wear. Although this may not seem like a safety issue, if the watch was not worn because it is not comfortable, then a safety issue is created because the patient is no longer being monitored. The comfortable Velcro strap solves this problem.

Another safety issue is that if the accelerometer is dropped, one of the components may break. This will cause the accelerometer to function incorrectly. The only way to tell if it works then is to see if the computer is recording data from the accelerometer or to have an actual seizure and see that the alarm does not go off. Both cases are very scary and can greatly endanger the patient.

The Bluetooth device used to relay information from the accelerometer to the alarm clock and to the computer has many risks. Bluetooth uses wireless microwave frequencies, which uses a short wavelength at a high frequency. These waves are capable of penetrating living tissue to the cellular level. Long term exposure to Bluetooth can result in multiple diseases including: cancer, leukemia, brain tumors, Alzheimer’s, autism, ADD, miscarriages, birth defects, autoimmune illnesses, multiple sclerosis, hair loss and depression. The FDA has approved Bluetooth Technology for use by consumers without any regulations or premarket. However, the FDA is beginning to further research the safety issues surrounding Bluetooth because felt a need study conducted by the Swedish National Institute for Working Life users using Bluetooth have a 240% greater risk of developing brain tumors on the same side of the head where they use their phone. Although the Bluetooth device is not located directly next to the patient’s ear, it still emits microwaves that come into contact with the patient’s head.

The alarm clock also has safety issues. One safety issue that the alarm clock has is that it will run on batteries. If the batteries end up leaking inside the alarm clock, it could ruin the alarm clock and prevent data from the accelerometer being relayed to a computer. Another danger of battery leakage is that potassium hydroxide to leak out of the battery cell, which could result in severe chemical burns to the patient if they remove the batteries. Lastly, if the batteries are
leaking and a fire occurs, the batteries are highly explosive and can cause a lot of damage by spraying potassium hydroxide all around.

The last danger involved with the seizure monitor is the computer that is receiving the data from the alarm clock. If the computer malfunctions or loses power, the computer will no longer record information from the seizure monitor.

5. Impact of Engineering Solutions

The Seizure Monitor Device could have a revolutionary impact on millions of people. The benefits of the design would impact engineering solutions on the global, economic, environmental, and societal levels. All over the world, parents of children who suffer from seizures choose to sleep in their child’s room rather than risk the chance of missing a nighttime seizure. Caregivers of epileptic patients suffer from sleep deprivation as a result of anxiety that they will not be present when a seizure occurs. Since not all seizures are characterized by audible changes in breathing, the use of baby monitors is not a good solution. The seizure monitors that consist of mattress pads may be somewhat effective, however these devices are limited to use only while sleeping. Furthermore, the mattress pads are not effective for use during sleepovers or vacations. By wearing the watch that will signal to an alarm when unusual prolonged movements are detected, the caregiver will certainly be warned of the emergency.

Since physicians will have complete records of the data recorded during the seizures, they will be better able to treat the patients. So how does this impact engineering solutions in an economic way? By accurately treating the patient, money and pharmaceutical resources will not be wasted on ineffective medications. Physicians will have a better idea of what type of seizures the patient is suffering from, and therefore will not waste money ordering unnecessary tests and procedures. The transmission of the data from the watch to the computer will save the patient from having to make a trip to the doctor’s office or hospital, and therefore will reduce medical costs. The projected cost of to produce one seizure monitor would be less than $400, and if the devices were to ultimately be manufactured in mass, the price would drastically decrease.

Although the seizure monitor won’t revolutionize environmental concerns, the design definitely takes an environmentally friendly approach. By sending the physiological data from the seizure electronically to the physician, the data will not need to be printed on paper. The lithium camera batteries also last longer, and this reduces battery waste.

The device offers great solutions in the societal context. People who suffer from nighttime seizures become extremely tired during the day. Patients who are sleep deprived and fatigued are more likely to have seizures. Thus, the pattern becomes a vicious cycle: the more frequently a patient suffers from seizures, the more tired he is, and therefore the likelihood of him having another seizure increases. By sending the compiled data to a physician’s computer, the physician can better diagnose the patient by putting him on a more appropriate medication, and thus making the quality of life for the patient (as well as the caregiver and family members) much better.

Another societal impact the device can make is on the patient’s everyday life. The patient can carry out his normal activities such as studying alone, taking a shower, cooking dinner, etc. without being afraid that a seizure might occur without anyone noticing. Looking closely at one of the above examples— if a patient were to suffer from a seizure while in the shower, so many dangers could persist. The person could hit his head or even worse, drown. Of course this is a worst case scenario, but by alarming a caregiver of the situation, the patient’s safety is greatly
enhanced and thus this plays a big role in solving engineering solutions in a societal context. This seizure monitor device can offer the patient a much greater independence.

6. Life-Long Learning

We’ve learned that epilepsy is a disease characterized by over forty types of seizures. Seizures are neurological disorders in which the brain is characterized by irregular electrical activity. We’ve learned about Tonic Clonic Seizures. There are three phases of the Tonic Clonic seizures: the aura, the tonic, and the clonic phase. When the patient experiences an aura, he may feel lightheaded, dizzy, and experience problems with vision and hearing. During the tonic phase, the patient loses consciousness and his muscles tense up. During the clonic stage, the patient’s muscles continuously contract and relax, resulting in convulsions. Some patients must be administered medication during their seizures, while other must simply be watched to ensure that they don’t injure themselves or choke on vomit.

We’ve learned about the existing methods and marketed products to detect seizures. Some people tend to use baby monitors, and hope that they will wake up upon hearing changes in breathing patterns of a seizing patient. Most seizure monitors on the market consist of a mattress pad that goes under the patient and thus detects movement of the patient while he sleeps.

We’ve learned about accelerometers and how they can function to detect change in one’s bodily movements. We’ve researched the capabilities of Bluetooth communication when considering wireless communication.

In terms of technical skills we’ve acquired, we’ve each learned different programs. Visio, Multisim, Ultiboard, AVR Studio, and LabVIEW have each been mastered, and we’ve learned how to set up our Team website on the BME page.

As a group, we’ve learned to work as a team. This includes collaborating on assignments, divvying up the work, scheduling meetings, making presentations, and adjusting to our teammate’s strengths and weaknesses. We’ve learned how to request information, advice, and assistance from faculty members and other experts. We’ve successfully conducted an interview/discussion with a patient who suffers from seizures. Subsequently, we’ve come to value the feedback of patients themselves just as much as the feedback from physicians.

7. Budget and Timeline

a. Budget

The group’s design project was funded through the Mechanical Engineering Department under the engineering professor, mentor, and client, Dr. John Bennett. Jacqueline Veronese was in charge of the administrative process of ordering the team’s parts and notifying the team upon arrival of packages. The group kept a detailed Excel sheet to organize the parts purchased and the budget spent, which can be seen in table 1. Hard copies of the receipts (or packing slips) were numbered and kept together in an organized notebook. Throughout the semester, the team made a variety of small changes to the design of the device, which resulted in additional parts being ordered. Changes to the design were a result of unforeseeable obstacles that faced the team as they began to build the seizure monitor.
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Total: 1068.67

Table 1. Seizure Monitor Budget.
7.2 Timeline
Please see Appendix C for the Microsoft Project timeline.

8. Team Member’s Contributions to the Project

8.1 Kathleen Cooney

Throughout the two semesters Katie Cooney has done a considerable amount of work for the Seizure Monitor. It was her job to do background research on epilepsy and tonic-clonic seizures. It’s imperative for the group to have a good understanding of the disorder in order to accurately detect and analyze it. Her research confirmed the need for a seizure monitor, as in the United States over three million people of all ages suffer from epilepsy. Despite medications becoming more effective, they are certainly not a solution. Seizures that go undetected can result in injury and sometimes even death.

It was Katie’s task to develop a way to alert the caregiver that a seizure is taking place. This was done in two separate ways. First she found C++ code to program the microcontroller to emit a beeping sound upon detection of seizure. Secondly, she designed LabVIEW code to send a text message to the caregiver’s cell phone upon detection of seizure. This took a lot of searching around and brainstorming before she was able to come up with a solution. It was also Katie’s task to research and develop initial LabVIEW programming to read the Bluetooth modules.

Throughout the semester it was typically her job to place orders through Jackie Veronese. It was also generally Katie’s job to remain connected with Dr. Bennett. She did this by sending email updates and arranging for meetings to receive his input on challenges we were facing. From January 10-15 she took the machine shop class. Since most of the project was electrical and computer coding, she weren’t in the machine shop all that much. However, the class proved to be useful during the last stage of our project when the team fabricated the alarm and watch. It was Katie’s job to put together the alarm clock. This involved creating appropriate holes on the casing for the Toggle Switch, the LEDs, and the speaker. It was also her job to put together the watch which involved creating a casing in which to place the watch PCB.

Throughout the semester the team took turns compiling the weekly reports into weekly power point presentations. It was Katie’s task to create the Operator’s Manual. She took photos to include in the manual for the ‘Parts and Accessories,’ and then described sections such as ‘Important Safety Instructions,’ ‘Features,’ ‘Maintenance,’ etc. Together, Katie and Adam Herman brainstormed the ‘Troubleshooting’ section. It was also her job to compile the Final Report. She did a decent amount of research on further applications for the device (as prompted to by the MBA students). She found there to be a possibility of extending the team’s device into the field of Parkinson’s disease. Katie’s research and ideas can be found in the Final Report. Together, Katie and Adam Herman made changes to the team’s original plans from December. It was also Katie’s job to create the power point Final Presentation which will be presented on Friday, April 22nd.

8.2 Adam Herman’s Contribution

Adam was responsible for designing the alarm and watch, including internal and external components. He learned to use Microsoft Visio to make schematics of the watch and alarm
components. Adam also learned to use Multisim and Ultiboard to design, test, and order the printed circuit boards for both the watch and alarm. This involved numerous hours in the lab working with the programs, learning through trial and error, posting on tech forums, and making contacts with company technicians. He was responsible to create each of the microcontrollers, the accelerometer, and the battery holder from scratch, which was a project in its own. He also built the circuits on a protoboard for ease in code-testing and he worked with Markman to establish a connection to the microcontroller and the Bluetooth module.

Upon completion of the watch and alarm circuits and receiving the PCB’s, Adam was responsible to solder the circuit components. Herman was given the responsibility of finding parts for the circuits that would suit the group’s design needs; this meant finding small, low-power components with sufficient speeds and memory. He read through countless datasheets, and made several company contacts in search of the right parts. Some of the chosen parts included surface mount technology, and this involved learning how to perform surface mount soldering. With time and patience, he was able to finish soldering the watch and alarm circuit boards with appropriate accuracy.

From the entrepreneurial side of the project, Adam had the task of attending MGMT 5635 where he developed a business plan with two UConn MBA students. A market and SWOT (strength, weakness, opportunity, and threat) analysis was performed. The business plan is almost complete and it shows promise as far as marketability.

Adam Herman also put substantial time into the final report and operator’s manual.

8.3 Adam Markman

For the Entrepreneurial Senior Design Project - Seizure Monitor, Adam Markman was in charge of the coding aspects of the product along with helping create the circuits. During the beginning of the semester, he spent a lot of time learning the C programming language along with how to use an AVR microcontroller. All of the past BME projects used PIC microcontrollers; however, Markman read that AVR is a more powerful microcontroller and he enrolled in a class that uses AVR microcontrollers. Adam Markman tried to be comfortable with basic microcontroller concepts such as analog-to-digital conversions, declaring I/O pins and how to send and receive data. In addition, he researched how to create a Bluetooth link between a Bluetooth attached to the microcontroller and a Bluetooth dongle. He also learned a lot of equations that were needed for the coding, such as A/D convert, Baud Rate equation and how to find the UBBR value. Before the group was able to get the Bluetooth, Markman created code for both the wrist watch and alarm clock. The wrist watch code takes a signal from the accelerometer, multiplexes it, and then sends it out to the alarm clock. The alarm clock then demultiplexes the signal and determines if a seizure is occurring. If a seizure is occurring, the information would be relayed to LabVIEW and it would analyze the data coming in and display it on a graph. Markman also worked on the LabVIEW code and created code to receive data from the alarm clock and display it in a graph. The graph displays the voltage output of the accelerometer vs. time.

Adam Markman also worked on the bread boards for the project. He helped Adam Herman connect the ATMega644PA to the bread board. He used the programmer from his class to program the microcontroller by plugging wires into the programmer to their corresponding parts on the microcontroller. Markman also used the oscilloscope to track the acceleration to get
9. Future Applications

The current status of the device does not accomplish detection of seizures through coding of the microcontrollers. This task was out of reach of the team’s computer coding skills as Biomedical Engineers. Based on the promise of the device, the team suggests that the project become a Senior Design Project for students in the Computer Science Engineering Department for the 2011-2012 Academic School Year. Both Adam Herman and Adam Markman will be affiliated with the UConn’s Engineering Programs as grad students, and thus they will be easily accessible to provide students with results of this year’s efforts.

Having been inspired by the MBA students of MGMT 5335 (Venture Planning, Management & Growth) the team brainstormed additional applications that the device might be useful for. The most promising idea involves the use of the device to monitor motion of tremor in patients suffering from Parkinson’s disease (PD).

PD is a degenerative disorder of the central nervous system (CNS) in which the number of dopaminergic neurons in the substantia nigra is significantly decreased. Unfortunately, PD cannot be diagnosed until at least 60% of these neurons have been destroyed, because prior to this amount of loss, symptoms are dormant. Symptoms of PD disease include shaking, rigidity, slowness of movement, and unusual gaits. Dyskinesia is the broad term which categorizes a spectrum of movement disorders ranging from small tremors to uncontrollable shaking. Current treatments include medications such as levodopa, however eventually the body stops responding to these drugs, and symptoms continue to get worse. Recent research has led to the discovery and use of deep brain stimulation (DBS). DBS is a surgical treatment which implants an electronic pacemaker into the chest of a patient with leads extending up through the neck into the brain. Electrical impulses are generated and sent into the brain to a target location of the substantia nigra. Ironically, even the top-notch neurosurgeons have trouble explaining the reasoning for why this procedure works, however results indicate that DBS benefits PD patients. Such benefits include a reduced tremor and less difficult performing motor activities. So how can our seizure monitor be of use to PD patients?

Our team proposes that the device could be utilized as an objective tool to measure the success of DBS surgery as it pertains to decreasing the motor disabilities experienced in patients suffering from PD. Our device could be worn by PD patients for a month prior to DBS. The coding would clearly have to be redesigned to detect for intensity and frequency of tremor motions rather than seizure motions. Data could be collected on the patient’s tremor characteristics prior to the surgery, and then the patient could wear the device for a month following surgery to detect what types of changes have occurred in terms of intensity and frequency of tremors. The device would offer a more objective and quantitative tool than simply asking a patient, “Do you feel you dyskinesia has improved or weakened? By what amount?” Furthermore, it is possible that the surgeon could use the device during surgery when he chooses the optimal settings for the patient. Different settings on the electrodes are required for different patients, and as of right now, there is no way of predicting which settings will be best. Therefore, our device could be worn by the patient during surgery to indicate which DBS settings provide the lowest amount of tremor in the patient’s muscles. Clearly more research
needs to be done on this topic; however our team feels that our device could definitely be useful in the field of PD and more specifically-DBS.

Additional applications that could be implemented in the future include a GPS locator in the watch. With this feature, the caregiver would always know the location of the patient, and in the event of a seizure, the caregiver would be able to respond quickly and directly. Also, adding a digital time display to the watch and alarm would improve the marketability of the product. With the digital time displays, the system is more complete, and more aesthetically appealing to the consumer; no longer is it strictly a medical device, but also an everyday functioning device. A further goal for this project would be to develop a Smartphone application so that the caregiver and doctor could access the seizure information directly on one’s handheld device. This may even rid the need for the alarm component, because in the event of a seizure, the smartphone could alert the caregiver that help is needed. This aspect also increases the product’s marketability because it adds a modern technological feature.

10. Conclusion

The seizure monitor device not only solves a biomedical engineering problem, but it also has high potential to be successful on the market. With over three million Americans suffering from seizures, the need to monitor these seizures is clearly present. The proposed device enhances the healthcare of patients suffering from seizures in two predominant ways. First off, it alarms the caregiver of the situation, and thus prevents the patient from becoming injured during an unnoticed medical emergency. Second, vital data recorded during the seizure will be sent to the physician, who can use this information to better diagnose and/or treat the patient. The trendy appearance of the watch will be extremely marketable. Once in manufacture, the seizure monitor device could be produced for less than $100. When comparing the cost of the watch to the benefits of the device, Team 23 strongly believes that consumers will be willing to make the purchase.
11. References


12. Acknowledgements

Team 23 would like to acknowledge the following people for their contributions to our project:

- Dr. John Bennett
- Dave Kaputa
- Dr. Enderle
- Emily Jacobs and Marek Wartenberg
- Dr. Peterson
- Amy Smith
- Dave Agerton & Sourabhdeep Khanna
- Jacqueline Veronese and the ME department
- Pete and Serge from the Machine Shop
13. Appendix

a. Updated Specifications
All specifications are up to date at this point.

b. Purchase Requisitions and Price Quotes
Team 23 is part of the Entrepreneurial Senior Design Program and therefore all parts ordering is done through the ME department, under Dr. John Bennett’s and Jacqueline Veronese’s supervision; purchase requisitions are not used for this process.

c. Timeline
Table 2 below shows the time line for Team 23’s project.

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<tr>
<td>48</td>
<td>LabVIEW: combine accelerometer info and calculations to recognize seizure occurrence</td>
<td>1 day?</td>
<td>Thu 1/20/11</td>
<td>Thu 1/20/11</td>
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<td>1</td>
<td>Schedule Meeting with Bennett</td>
<td>6 days</td>
<td>Fri 1/21/11</td>
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<td>9</td>
<td>Purchase Bluetooth (3)</td>
<td>6 days?</td>
<td>Fri 1/21/11</td>
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<td>36</td>
<td>Build alarm design on protoboard</td>
<td>2 days</td>
<td>Thu 1/27/11</td>
<td>Fri 1/28/11</td>
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<td>27</td>
<td>Test Bluetooth range</td>
<td>3 days</td>
<td>Mon 1/31/11</td>
<td>Wed 2/2/11</td>
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<td>19</td>
<td>Test Watch voltages on protoboard</td>
<td>8 days</td>
<td>Wed 1/26/11</td>
<td>Fri 2/4/11</td>
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<td>20</td>
<td>Test watch output signal on protoboard</td>
<td>10 days</td>
<td>Wed 1/26/11</td>
<td>Tue 2/8/11</td>
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<td>38</td>
<td>Test voltages on protoboard</td>
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<td>Mon 1/31/11</td>
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<td>21</td>
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<td>3 days</td>
<td>Wed 2/9/11</td>
<td>Fri 2/11/11</td>
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<td>6</td>
<td>Determine accelerometer outputs that correspond to seizure activities</td>
<td>10 days</td>
<td>Tue 2/1/11</td>
<td>Sun 2/13/11</td>
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<td>5</td>
<td>Bandpass filter for accelerometer</td>
<td>10 days</td>
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<td>Mon 2/14/11</td>
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<td>16</td>
<td>Purchase casing for watch</td>
<td>6 days</td>
<td>Mon 2/14/11</td>
<td>Mon 2/21/11</td>
<td>21</td>
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<td>17</td>
<td>Design Watch in Multisim</td>
<td>22 days</td>
<td>Mon 1/24/11</td>
<td>Tue 2/22/11</td>
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<td>Purchase Microcontroller</td>
<td>26 days</td>
<td>Sun 1/23/11</td>
<td>Fri 2/25/11</td>
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<td>Mon 1/31/11</td>
<td>Fri 2/25/11</td>
<td>9</td>
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<td>7</td>
<td>Program to connect to Bluetooth</td>
<td>20 days</td>
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<td>End Date</td>
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<td>Learn to use MPLAB IDE 2</td>
<td>17 days</td>
<td>Tue 2/8/11</td>
<td>Wed 3/2/11</td>
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<tr>
<td>Calculate watch resistor values</td>
<td>6 days</td>
<td>Wed 2/23/11</td>
<td>Wed 3/2/11</td>
<td>17</td>
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<td>Order PCB Components for watch</td>
<td>6 days</td>
<td>Wed 2/23/11</td>
<td>Wed 3/2/11</td>
<td>17</td>
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<tr>
<td>Calculate watch capacitor values</td>
<td>1 day?</td>
<td>Thu 3/3/11</td>
<td>Thu 3/3/11</td>
<td>17</td>
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<tr>
<td>Design alarm in multism</td>
<td>17 days</td>
<td>Tue 2/15/11</td>
<td>Wed 3/9/11</td>
<td>10</td>
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<td>Present project to MBA class</td>
<td>28 days</td>
<td>Tue 2/1/11</td>
<td>Thu 3/10/11</td>
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<td>Order Watch PCB</td>
<td>6 days</td>
<td>Thu 3/3/11</td>
<td>Thu 3/10/11</td>
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<td>Read Microcontroller Tutorials</td>
<td>11 days</td>
<td>Mon 2/28/11</td>
<td>Mon 3/14/11</td>
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<td>Solder watch PCB components</td>
<td>2 days</td>
<td>Fri 3/11/11</td>
<td>Mon 3/14/11</td>
<td>24</td>
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<td>Connect LabVIEW to Bluetooth from alarm clock</td>
<td>10 days</td>
<td>Tue 3/1/11</td>
<td>Mon 3/14/11</td>
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<tr>
<td>LabVIEW: Program to display type of seizure</td>
<td>1 day?</td>
<td>Tue 3/15/11</td>
<td>Tue 3/15/11</td>
<td>28</td>
<td></td>
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<td>LabVIEW: Create Idle Condition</td>
<td>1 day?</td>
<td>Wed 3/16/11</td>
<td>Wed 3/16/11</td>
<td>49</td>
<td></td>
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<td>LabVIEW: Create Front Panel</td>
<td>1 day?</td>
<td>Wed 3/16/11</td>
<td>Wed 3/16/11</td>
<td>49</td>
<td></td>
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<td>LabVIEW: Implement phone call</td>
<td>1 day?</td>
<td>Thu 3/17/11</td>
<td>Thu 3/17/11</td>
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<td>Troubleshoot seizure monitor/alarm device/LabVIEW Program</td>
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<td>Thu 3/17/11</td>
<td>Thu 3/17/11</td>
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<td>LabVIEW: Catalog intensity of seizure</td>
<td>1 day?</td>
<td>Fri 3/18/11</td>
<td>Fri 3/18/11</td>
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<td>LabVIEW: Catalog duration of seizure</td>
<td>1 day?</td>
<td>Mon 3/21/11</td>
<td>Mon 3/21/11</td>
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<td>Task Description</td>
<td>Days</td>
<td>Start Date</td>
<td>End Date</td>
<td>Percentage</td>
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<td>LabVIEW: Catalog date and time</td>
<td>1 day?</td>
<td>Tue 3/22/11</td>
<td>Tue 3/22/11</td>
<td>53</td>
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<td>LabVIEW: Clean program to reduce memory</td>
<td>1 day?</td>
<td>Thu 3/24/11</td>
<td>Thu 3/24/11</td>
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<td>Program Microcontroller</td>
<td>23 days</td>
<td>Tue 3/1/11</td>
<td>Thu 3/11</td>
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<td>Place PIC in alarm clock</td>
<td>1 day?</td>
<td>Thu 3/31/11</td>
<td>Thu 3/31/11</td>
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<td>Optimize microcontroller code</td>
<td>4 days</td>
<td>Mon 3/28/11</td>
<td>Thu 3/31/11</td>
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<td>Program to Interpret accelerometer data</td>
<td>23 days</td>
<td>Tue 3/1/11</td>
<td>Thu 3/11</td>
<td></td>
<td></td>
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<tr>
<td>Calculate Alarm resistor values</td>
<td>17 days</td>
<td>Thu 3/10/11</td>
<td>Fri 4/1/11</td>
<td>32</td>
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<td>Calculate Alarm Capacitor values</td>
<td>17 days</td>
<td>Thu 3/10/11</td>
<td>Fri 4/1/11</td>
<td>32</td>
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<td>Make LabVIEW display data on chart</td>
<td>3 days</td>
<td>Thu 3/31/11</td>
<td>Mon 4/4/11</td>
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<tr>
<td>Convert Alarm in Multisim to Ultiboard</td>
<td>1 day?</td>
<td>Mon 4/4/11</td>
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<td>Order Alarm PCB</td>
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<td>Order Alarm casing</td>
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<td>Solder alarm PCB components</td>
<td>1 day?</td>
<td>Fri 4/8/11</td>
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<td>Test alarm output signal on protoboard</td>
<td>7 days</td>
<td>Fri 4/1/11</td>
<td>Mon 4/11/11</td>
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<td>Assemble seizure alarm</td>
<td>1 day?</td>
<td>Mon 4/11/11</td>
<td>Mon 4/11/11</td>
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<td>Optimize LabVIEW code</td>
<td>9 days</td>
<td>Fri 4/1/11</td>
<td>Wed 4/13/11</td>
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<td></td>
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<tr>
<td>Build watch design on Protoboard</td>
<td>22 days</td>
<td>Tue 3/15/11</td>
<td>Wed 4/13/11</td>
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<td>Assemble the watch</td>
<td>3 days</td>
<td>Thu 4/14/11</td>
<td>Mon 4/18/11</td>
<td>18</td>
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<tr>
<td>Verify time and Date work on the watch</td>
<td>2 days</td>
<td>Tue 4/19/11</td>
<td>Wed 4/29/11</td>
<td>29</td>
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<tr>
<td>Verify watch functionality</td>
<td>2 days</td>
<td>Thu 4/21/11</td>
<td>Fri 4/22/11</td>
<td>15</td>
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<td>Write Final Report</td>
<td>16 days</td>
<td>Fri 4/1/11</td>
<td>Fri 4/22/11</td>
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<tr>
<td>Prepare Final Presentation</td>
<td>16 days</td>
<td>Fri 4/1/11</td>
<td>Fri 4/22/11</td>
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<tr>
<td>Disassemble Alarm Clock</td>
<td>2 days</td>
<td>Mon 4/25/11</td>
<td>Tue 4/26/11</td>
<td>30</td>
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<tr>
<td>Calibrate Accelerometer</td>
<td>44 days</td>
<td>Tue 3/1/11</td>
<td>Fri 4/29/11</td>
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<td>Prepare Demonstration</td>
<td>6 days</td>
<td>Fri 4/22/11</td>
<td>Fri 4/29/11</td>
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<tr>
<td>Meet with Client to Present the Finished Product</td>
<td>6 days</td>
<td>Mon 4/25/11</td>
<td>Mon 5/2/11</td>
<td>61</td>
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<tr>
<td>Go to ESDP Class</td>
<td>80 days</td>
<td>Mon 1/17/11</td>
<td>Fri 5/6/11</td>
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<tr>
<td>Create business plan</td>
<td>59</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
d. Clonic Business Plan
The Business plan, as completed and presented by Adam Herman, Dave Agerton, and Sourabhdhip Khanna in MGMT 5335 Venture Planning.

Executive Summary

Over three million Americans suffer from spontaneous seizures, and of this number, children have a one in one hundred chance of having epilepsy-recurring seizures. Patients who suffer from seizures can lose consciousness, severely injure themselves, experience extreme fatigue, and even undergo incontinent activity or vomit. Physicians, nurses, parents, and other caregivers are in dire need for a method to monitor and diagnose seizures on a 24-hour schedule.

Clonic is a medical alert and diagnostic system that can significantly improve the lives of epileptic patients. First and foremost, the device serves to revolutionize patient safety for those who suffer from epilepsy and other seizure disorders. It does this by providing non-invasive, 24-hour seizure detection to epileptic patients and their caregivers. Utilizing a wirelessly transmitting watch, any motor seizure that occurs automatically alerts an alarm, which will notify a caregiver that a seizure is in progress. The seizure’s intensity, duration, and time of occurrence is recorded and sent to a computer, PDA, or Smartphone for analysis by a doctor. The doctor can then study a patient’s seizure activity, and prescribe medication accordingly.

Production of the device will be outsourced to CIRTEC Medical Systems in East Longmeadow, MA. Each monitor will cost $80 to manufacture and will sell for $900 per unit. The devices will be distributed through Cardinal Health or McKesson. We will market our product to healthcare facilities such as hospitals and personal assisted living homes. Our R&D will focus on further uses for the device, including and not limited to, monitoring tremors in patients suffering from Parkinson’s disease.

Company Overview

History and Current Status
Three biomedical engineering students at the University of Connecticut first introduced Clonic as a senior design idea in September of 2010. The idea was accepted as a project in the Entrepreneurial Senior Design Program and funded by Dr. John Bennett in the mechanical engineering department. The design of the device, including the circuitry and physical composition is completed. The microcontroller code and LabVIEW analysis code is being passed on as a continuation project to a senior design group in the electrical or computer-science engineering department. Our vision is that the code will be completed and integrated into the device within the next school year. By the end of 2013, Clonic will be used in hospitals to monitor, diagnose, and mitigate seizures and their consequences.

Mission
Clonic will enhance the quality of life of patients suffering from epileptic motor seizures by providing 24-hour detection and diagnostic assistance, preventing future seizures, and reducing hospital and patient costs. We will deliver value to patients, consumers, and stakeholders by working in partnership with healthcare providers and managed care organizations.
Strategy
The *Clonic* business model implements a differentiation strategy by focusing on R&D, marketing, and sales. The initial focus will be on delivering products to hospitals and other healthcare facilities, where active patient monitoring occurs. Upon success in hospitals, the company will make efforts to penetrate the individual consumer market.

Goals and Objectives
The most important immediate future goal is the successful integration of the microcontroller code into the watch and alarm components of *Clonic*. Upon achievement of this milestone and each one thereafter, our product will attract more healthcare facilities as we ramp up our sales force.

<table>
<thead>
<tr>
<th>Year</th>
<th>Goal</th>
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<tbody>
<tr>
<td>2012</td>
<td>Completion of microcontroller code and implementation into Clonic system</td>
</tr>
<tr>
<td>2014</td>
<td>Five strategically placed sales reps across the country</td>
</tr>
<tr>
<td>2015</td>
<td>Ten strategically placed sales reps across the country. Also, beginning of R&amp;D for the future implementation of the Clonic system into monitoring and diagnosis of other diseases and disorders</td>
</tr>
<tr>
<td>2016</td>
<td>Exit Strategy</td>
</tr>
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</table>

Product

Features, Benefits, and Competitive Advantages
Tonic-clonic or motor seizures can be detrimental to a patient’s health, resulting in loss of consciousness, exhaustion, nausea, vomiting, and inadvertent injury. By using the seizure monitor device *Clonic*, a caregiver will be notified of the seizure and can therefore help by providing the necessary medical assistance. Secondly, the device provides vital physiological information through specific measurements of seizure activity to a patient’s physician. The physician can learn more about the seizure’s duration, severity, and frequency. This information is vital in providing the correct medical treatment. Not only does the device offer enhanced safety and medical treatment for the patient, but it is also small in size and aesthetically pleasing. Current devices consist of mattress pads and thus can only monitor seizures during sleep, which is only half the battle, as patients are at a higher risk if a seizure occurs in an unfamiliar and potentially dangerous area.

Convenience: Monitoring and diagnosing medication for seizures is difficult. Most physicians currently use time consuming and invasive methods to properly diagnose and prescribe medication to those who experience seizures. Healthcare facilities currently use video surveillance techniques, which require constant monitoring. If a patient were to use the restroom, go for a walk, or simply stand up in their room, this method fails to recognize seizures. *Clonic* has the 24-hour ability to monitor seizures. The wristwatch portion of the system allows patients to go where they please. This factor provides comfort in knowing no seizure will go undetected and this is attractive to the patient, nurse, and doctor. *Clonic* is also completely non-
invasive, which reduces costs for a patient who would normally require brain stimulation and electrode monitoring.

**Cost:** As far as monitoring medical devices are concerned, $900 dollars per unit is extremely cheap. This cost will be appealing to healthcare facilities. The cost of mattress pads, video surveillance, and the accompanying personnel to monitor the video along with the risk of patient injury is much higher than the cost of the *Clonic* system. Not only is the buyer receiving a monitoring device, but one must keep in mind that this is the only device that outputs vital seizure information to a user-friendly software program.

**Immediate Detection and Diagnosis:** The *Clonic* system provides immediate feedback when a patient experiences a seizure. The instant seizure activity initiates, an alarm alerts the caregiver that a seizure is in progress using both visual and audio stimulus. This data is also simultaneously sent to a user-friendly LabVIEW program, which can run on any computer or mobile device with Windows capabilities. What is important to realize is that with this technology, no seizure goes undetected, and a qualified physician can easily track a patient’s seizure history.

**Current Stage of Development**
After one school year of research and development, the senior design team was able to complete the physical design, internal circuitry, preliminary microcontroller, and LabVIEW code. This was completed with expenses reaching only $1064.36. The project is being passed on as a continuation project to a senior design team in either electrical or computer-science engineering. The successors will finalize the microcontroller code, including two-way Bluetooth communication between each device, accurate seizure detection, and possible addition of a GPS locator. They will also investigate a Smartphone application.

We plan to outsource the entire FDA clearance process to Emergo Group. This group is an ISO registered medical and IVD device consulting firm with offices worldwide. The FDA clearance process should take less than two years as it is considered a Class 1 device.

**Proprietary Position**
Upon successful completion of the continued project by a 2011-2012 senior design team, a patent will be requested. A patent attorney, who will be decided upon when the product is completed, will manage the patent process. By going outside of the University of Connecticut to patent the *Clonic* system, we are saving the company 33.33% equity share, which is the share specified in the royalty share policy created by the University.

**Expansion Possibilities**
There exist many exciting opportunities for expansion into ancillary markets, including at-home products, development of alternative disease monitoring techniques, and a Bluetooth technology based GPS locator for tagging animals. The device shows promise in monitoring tremors related to Parkinson’s disease, and this opens up a whole new market for *Clonic*. Another market *Clonic* hopes to penetrate is the at-home monitoring of seizures, in particular for patients under the age of 18. Children are at a higher risk of experiencing seizures, and if properly monitored, this will improve diagnosis and reduce large amounts of stress associated with parental supervision over children with epilepsy.
Market and Competitive Analysis

CDC estimates that about 1 out every 100 people in the United States have experienced an unprovoked seizure or been diagnosed with epilepsy and nearly 140,000 Americans develop the condition each year. For about 80 percent of those diagnosed with epilepsy, seizures can be controlled with modern medicines and surgical techniques. However, about 25 to 30 percent of people – about 600,000 people – with epilepsy will continue to experience seizures even with the best available treatment. Doctors call this situation intractable epilepsy. Having a seizure does not necessarily mean that a person has epilepsy. The total indirect and direct cost of epilepsy in the United States is estimated to be $15.5 billion. This estimate is based on a reported cost of $12.5 billion in 1995 converted to 2004 dollar value using Bureau of Labor Statistics data.

One recent study that followed patients for an average of 8 years found that only 33 percent of people have a second seizure within 4 years after an initial seizure. People who did not have a second seizure within that time remained seizure-free for the rest of the study. For people who did have a second seizure, the risk of a third seizure was about 73 percent on average by the end of 4 years.

In addition, medical devices represent a $350 billion global business, with most of the major companies based in the U.S., including Medtronic Inc., St. Jude Medical Inc. and Baxter International Inc.

Competitive Environment

**Video Monitoring:** Special rooms are prepared where video cameras are installed and monitored by nurses/attendants. This can be an expensive proposition as each room per patient needs to be equipped with cameras and still there is no continuous supervision. A seizure could occur in bathrooms or at night where a patient might fall and could not be seen on the camera.

**Bed Occupancy Detection:** There are a few products currently available that are similar to our proposed seizure monitor. The first one is the Medpage ST-2. It is priced at $680/unit. The Medpage ST-2 is a monitor designed to detect and sound an alarm from a sleeping person experiencing regular muscular convulsions such as an epileptic seizure or convulsions caused by hypoglycaemia in a diabetic person. The ST-2 monitor provides dual detection functionality, seizure monitoring and bed occupancy detection. A sensor is placed under the user’s mattress, bed or cot. During sleep movements from the patient are monitored by the ST-2 microprocessor. Prolonged irregular movements result in an alarm being generated by the monitor with a signal transmitted to the alarm pager or other alarm in use with the ST-2 monitor. The transmitter also has a call button and a socket that allows connection similar to a standard hospital nurse call switch. The transmitter also has some specialized easy operation switches for the physically disabled. Finally, it has built in tone alarms that can be set to produce a sound alarm when a bed seizure monitor has detected a seizure or the person leaving their bed.

Another product is the MP5 - Complete System - Bed Motion Alarm for convulsive movement such as Epilepsy Seizures. It is priced at $365/unit. This system works by detecting shaking or jerking movements such as those encountered during convulsive seizures as well as sounds/noises. It will not detect mild seizures, and should not be used for people under 56lbs. However, if the mattress is thick, or the bed is large, the user would need to use two sensors to offer the same system features and functions. The system is set up by placing the
sensors between the mattress and box spring. It is essential that the box spring be under the heaviest part of the user’s body. From there, the pagers are turned on and given to the care takers and the sensitivity controls set. The bed monitor communicates with the wireless pagers up to a distance of approximately 328 feet. Another product is the Emfit Nocturnal Tonic-Clonic Seizure Monitor. It is priced at $1,072/unit. The Emfit Movement monitor consists of a flexible and durable bed sensor (L-4060SL), which is placed under the mattress, and a bed-side monitor (D-2090-2G). The Movement Monitor detects when a person has continuous quick-paced movements over a preset period of time and then triggers a notification. The system also notices light movements, thus making it equally suitable for small children. The control unit can be placed next to the bed or on the wall using the included fastening bracket. It is operated with 2 standard AA size 1.5 V batteries.

**Driving Forces and Trends**

The vagus nerve stimulator was approved by the U.S. Food and Drug Administration (FDA) in 1997 for use in people with seizures that are not well-controlled by medication. The vagus nerve stimulator is a battery-powered device that is surgically implanted under the skin of the chest, much like a pacemaker, and is attached to the vagus nerve in the lower neck. This device delivers short bursts of electrical energy to the brain via the vagus nerve. On average, this stimulation reduces seizures by about 20 - 40 percent. Patients usually cannot stop taking epilepsy medication because of the stimulator, but they often experience fewer seizures and they may be able to reduce the dose of their medication. Side effects of the vagus nerve stimulator are generally mild but may include hoarseness, ear pain, a sore throat, or nausea. Adjusting the amount of stimulation can usually eliminate most side effects, although the hoarseness typically persists. The batteries in the vagus nerve stimulator need to be replaced about once every 5 years; this requires a minor operation that can usually be performed as an outpatient procedure. Several new devices may become available for epilepsy in the future. Researchers are studying whether transcranial magnetic stimulation (TMS), a procedure which uses a strong magnet held outside the head to influence brain activity, may reduce seizures. They also hope to develop implantable devices that can deliver drugs to specific parts of the brain. Preliminary research suggests that stem cell transplants also may prove beneficial for treating epilepsy. Research showing that the brain undergoes subtle changes prior to a seizure has led to a prototype device that may be able to predict seizures up to 3 minutes before they begin. If this device works, it could greatly reduce the risk of injury from seizures by allowing people to move to a safe area before their seizures start. This type of device also may be hooked up to a treatment pump or other device that will automatically deliver an antiepileptic drug or an electric impulse to forestall the seizures.

**Operating Strategies**

**Production Strategy**

We will outsource product manufacturing to CIRTEC Medical Systems in East Longmeadow, MA. CIRTEC provides us with comprehensive manufacturing services such as assembly and functional testing; process mapping, design, and optimization; supply chain management solutions; lot history record documentation; and KanBan utilization in time assembly and cost containment. CIRTEC estimates that the fully integrated, ready to ship seizure monitor device will cost $80 per unit to manufacture.
Pricing and Distribution Strategy
Medical devices are sometimes purchased by healthcare facilities but are typically done through a third party distributor such as McKesson or Cardinal Health. We will utilize these distributors in order to ensure quick and consistent product delivery. Healthcare facilities utilize the seizure monitor devices on their patients and are then reimbursed by the patient’s insurance company at a pre-negotiated rate. Reimbursement rates for covered services are initially determined by Medicare. Commercial insurance companies then establish their own reimbursement rates based upon Medicare reimbursement.

One seizure monitor unit will sell to a healthcare facility for $900/unit. This price provides several incentives for the payor. One is that this device provides 24 hour patient monitoring while competitors’ products only monitor while the patient sleeps. The ability of a caregiver to monitor the patient 24 hours per day can protect the patient from additional trauma as a result of a seizure. A reduction of seizure induced trauma will result in lower health care costs for the payor. Second, this is the only seizure monitor device that can be used by healthcare physicians as a diagnostic tool to mitigate the occurrence of future seizures. Last year, nearly 1.4 million hospital stays in the U.S. identified epilepsy or convulsions as a diagnosis. About 277,000 stays had epilepsy as the principal reason for hospitalization, totaling nearly $1.8 billion in hospital costs. Considering the average length of stay for a patient with epilepsy is 3.6 days, the cost per hospitalization is $6,600. Because this is the only seizure monitor device that can be used to prevent future seizures, the result is reduced hospital stays and costs incurred by the payor.

Research and Development Strategy
We are committed to funding R&D because we view this as the foundation of being a sustainable company. Additional applications that could be implemented in the future include a GPS locator in the watch. With this feature, the caregiver would always know the location of the patient, and in the event of a seizure, the caregiver would be able to respond quickly and directly. Also, adding a digital time display to the watch and alarm would improve the marketability of the product. With the digital time displays, the system is more complete, and more aesthetically appealing to the consumer; no longer is it strictly a medical device, but also an everyday functioning device. A further goal for this project would be to develop a smart phone application so that the caregiver and doctor could access the seizure information directly on one’s handheld device. This may even rid the need for the alarm component, because in the event of a seizure, the smart phone could alert the caregiver that help is needed.

In addition, the most promising idea involves the use of the device to monitor motion of tremor in patients suffering from Parkinson’s disease (PD). PD is a degenerative disorder of the central nervous system (CNS) in which the number of dopaminergic neurons in the substantia nigra is significantly decreased. Unfortunately, PD cannot be diagnosed until at least 60% of these neurons have been destroyed, because prior to this amount of loss, symptoms are dormant. Symptoms of PD disease include shaking, rigidity, slowness of movement, and unusual gaits. Dyskinesia is the broad term which categorizes a spectrum of movement disorders ranging from small tremors to uncontrollable shaking. Current treatments include medications such as levodopa, however eventually the body stops responding to these drugs, and symptoms continue to get worse. Recent research has led to the discovery and use of deep brain stimulation (DBS). DBS is a surgical treatment which implants an electronic pacemaker into the chest of a patient with leads extending up through the neck into the brain. Electrical impulses are generated and
sent into the brain to a target location of the substantia nigra. Ironically, even the top-notch neurosurgeons have trouble explaining the reasoning for why this procedure works, however results indicate that DBS benefits PD patients. Such benefits include a reduced tremor and less difficult performing motor activities. So how can our seizure monitor be of use to PD patients? Our team proposes that the device could be utilized as an objective tool to measure the success of DBS surgery as it pertains to decreasing the motor disabilities experienced in patients suffering from PD. Our device could be worn by PD patients for a month prior to DBS. The coding would clearly have to be redesigned to detect for intensity and frequency of tremor motions rather than seizure motions. Data could be collected on the patient’s tremor characteristics prior to the surgery, and then the patient could wear the device for a month following surgery to detect what types of changes have occurred in terms of intensity and frequency of tremors. The device would offer a more objective and quantitative tool than simply asking a patient, “Do you feel you dyskinesia has improved or weakened and by what amount?” Furthermore, it is possible that the surgeon could use the device during surgery when he chooses the optimal settings for the patient. Different settings on the electrodes are required for different patients, and as of right now, there is no way of predicting which settings will be best. Therefore, our device could be worn by the patient during surgery to indicate which DBS settings provide the lowest amount of tremor in the patient’s muscles. Clearly more research needs to be done on this topic; however our team feels that our device could definitely be useful in the field of PD and more specifically-DBS.

**Personnel, Sales, and Marketing Strategy**
We plan to partner with a third party contract sales force to sell the units. This will allow us to utilize sales representatives with established customer relationships and sales experience in the medical device industry. In addition to selling the unit, the sales reps will be responsible for educating healthcare professionals and staff on the appropriate utilization of the kit. The management team will also be thoroughly involved in the sales process.
We will initially locate sales reps in areas of the country with the highest revenue potential, beginning with five strategically placed sales reps by 2014, and expanding to 10 reps by 2015. The efforts of the sales force will be supported by a website and toll free number that provides customers a convenient method of placing direct orders.
We will employ a marketing strategy that targets physicians, healthcare facilities, and third party payors, which is similar to the strategy utilized by pharmaceutical, medical device, and durable medical goods industries. We will also present scientific evidence associated with the device at medical conferences and trade shows.

**Management Team**
The CEO is responsible for daily operations, strategic planning, stakeholder relationship building, and overall company organization. The CFO is responsible for accounting functions, company financials, company procurement, and controller functions. The VP of marketing is responsible for marketing functions, product branding, and marketing the new product development. Each of the program advisors is responsible for maintaining communication between the University of Connecticut and the company, directing the patent process, and promoting the entrepreneurial senior design program to future undergraduates and investors.
Management Team | Relevant Qualifications
--- | ---
Adam Herman  
Chief Executive Officer | Graduate of University of Connecticut
David Agerton  
Chief Financial Officer | Graduate of University of Connecticut, MBA
Sourabdeep Khanna  
President of Marketing | Graduate of University of Connecticut, MBA
John Bennett, Ph.D.  
Co-Program Advisor | University of Connecticut Entrepreneurial Senior Design Program Advisor - Mechanical Engineering Department
Luke Weinstein, Ph.D.  
Co-Program Advisor | University of Connecticut Entrepreneurship Assistant Professor in Residence - Management Department

Compensation
The management team, minus the program advisors, will receive a base salary as seen in Appendix A. The minimal salaries will increase with time, as the company’s success is monitored. A re-evaluation of the members’ salaries will occur after year two, after which an incentive plan in line with the company goals will be implemented. As this is a University project and a continuation project, the compensation plan is preliminary and doesn’t include the team members from the second senior design team.

Offering

Offering and Value Investment
We will be seeking $250,000 in return for a 50% ownership stake for FDA application and clearance, clinical trial, and market launch. In addition, the management team will provide $50,000 toward prototype refinement, patent application process, and initial manufacturing costs. The total of these investments will allow us to successfully bring the seizure monitor device to full market launch before the end of 2013. We are also exploring available grant opportunities. We project 2016 EBITDA of $16.9 million based on $45.3 million in revenue from projected sales of 50,400 units. At six times EBITDA, a discounted industry standard derived from the P/E ratio of microcap medical equipment and supply companies, we will be valued at $101 million.

Exit Strategy
We view acquisition by a major medical company as the preferred exit strategy. Acquisitions are common in the industry and typically occur when a company reaches a value creating milestone. Our major milestones are prototype completion, FDA clearance, and market launch. Upon achievement of each milestone, we will entertain offers to sell the technology or to enter into a
licensing agreement with larger companies. This means that there are many opportunities to provide an exit for investors.

**Critical Risks**

Our team has been able to identify a few risks which might hamper the success of this project.

**Safety Issues**

There are a few safety issues associated with the Seizure monitor. The first involves the watch. The watch may not function properly in very wet conditions such as heavy rain. A malfunction could result in an incorrect reading or no reading at all. Moreover, the watch should never overheat and burn the patient’s wrist. If the watch begins to heat up, a problem is likely occurring within the circuit and the user must remove the watch. The watch must also be comfortable to wear. Although this may not seem like a safety issue, if the watch was not worn because it is not comfortable, then a safety issue is created because the patient is no longer being monitored. The comfortable Velcro strap solves this problem.

Another safety issue is that if the accelerometer is dropped, one of the components may break. This will cause the accelerometer to function incorrectly. The only way to tell if it works then is to see if the computer is recording data from the accelerometer or to have an actual seizure and see that the alarm does not go off. Both cases are very scary and can greatly endanger the patient.

The Bluetooth device used to relay information from the accelerometer to the alarm clock and to the computer has many risks. Bluetooth uses wireless microwave frequencies, which uses a short wavelength at a high frequency. These waves are capable of penetrating living tissue to the cellular level. Long term exposure to Bluetooth may result in multiple diseases including: cancer, leukemia, brain tumors, Alzheimer’s, autism, ADD, miscarriages, birth defects, autoimmune illnesses, multiple sclerosis, hair loss and depression. The FDA has approved Bluetooth Technology for use by consumers without any regulations or premarket. However, the FDA is beginning to further research the safety issues surrounding Bluetooth because of a study conducted by the Swedish National Institute for Working Life. The study stated that people using Bluetooth have a 240% greater risk of developing brain tumors on the same side of the head where they use their phone. Although the Bluetooth device is not located directly next to the patient’s ear, it still emits microwaves that come into contact with the patient’s head.

The alarm clock also has safety issues. One safety issue that the alarm clock has is that it will run on batteries. If the batteries end up leaking inside the alarm clock, it could ruin the alarm clock and prevent data from the accelerometer being relayed to a computer. Another danger of battery leakage is that potassium hydroxide to leak out of the battery cell, which could result in severe chemical burns to the patient if they remove the batteries. Lastly, if the batteries are leaking and a fire occurs, the batteries are highly explosive and can cause a lot of damage by spraying potassium hydroxide all around.

The last danger involved with the seizure monitor is the computer that is receiving the data from the alarm clock. If the computer malfunctions or loses power, the computer no longer records information from the seizure monitor.
Regulatory
Our device falls into Class I devices, which are defined as non-life sustaining because these products are the least complicated and their failure poses little risk. They are exempted from 510(K) and GMP requirements.

Appendices
Appendix A: Financial Assumptions
1. Revenue projections: Sales price is $900/unit. Estimates include selling 20 units per healthcare facility. Estimates that a sales person will be able to initially sell to 4 healthcare facilities per month.
2. COGS: Estimated at $80/unit.
3. Salary expense: Two individuals on staff include CEO, CFO, and VP of Marketing. The annual starting salary in 2012 for the CEO is $20,000 and $10,000 for the CFO and VP of Marketing. Beginning in 2013, the annual salary for the CEO will increase to $30,000 and $25,000 for the CFO and VP of Marketing. The salaries will increase five percent per year thereafter.
4. Employee benefits, such as healthcare and disability insurance, are calculated at 20% of salaries. FICA and Medicare taxes at 7.65%.
5. Professional Services: Outside sales force estimated at $55/hr averaging 160 hours per sales rep per month. There will be five sales reps by the beginning of 2013. This number will increase to 10 sales reps by the beginning of 2014. Attorney fees will be $500 per month. Issuance of a patent in 2011 is estimated at $20,000.
6. Business liability insurance estimated at $4,200 per year for $10M liability insurance.
7. Allowance for bad debt: estimated expense is 1%.
8. Rent expense: We will work out of our home. $3,500 per month includes rent, utilities, and insurance.
9. Other expenses: Estimated at $100,000 for prototype refinement, clinical trials, FDA application, and manufacturing expenditures in 2011. Estimated at 10% revenue for the following years.
10. Marketing expense: Estimated at 30% or revenues to include warehousing and distribution.
11. Shipping and Delivery: Estimated at 5% of revenues.
12. Travel Expense: $2,500/month
13. Research and Development: Projected at 5% of revenues beginning in 2014.
14. Accounts Receivable: Estimated that 20% of sales will not be collectable in the quarter billed, and 1% will not be collected in the second quarter billed.
15. Accounts Payable: Estimated at 75% of expenses in the period.
Appendix B

Pro Forma Income Statement

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\(^1\) NIND Epilepsy Information Page: [http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#175283109](http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#175283109)

\(^2\) CDC Epilepsy Information page: [http://www.cdc.gov/epilepsy/basics/faqs.htm](http://www.cdc.gov/epilepsy/basics/faqs.htm)

\(^3\) NIND Epilepsy Information Page: [http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#175283109](http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#175283109)


\(^5\) NIND Epilepsy Information Page: [http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#175283109](http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#175283109)