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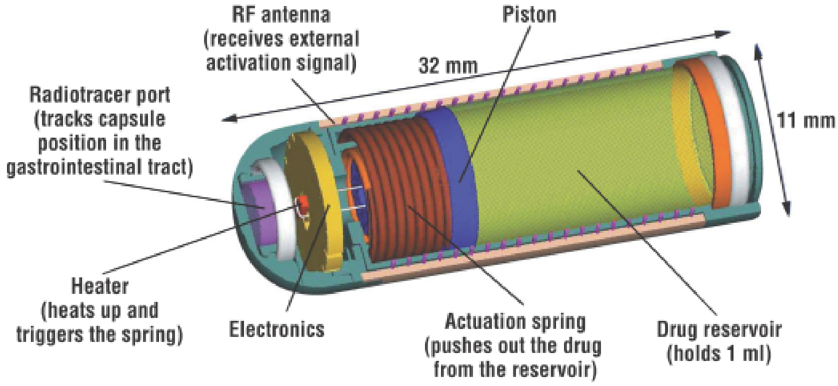

Senior Design

Swallowable Capsule II: Final Report

Submission Date: April 25, 2012

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Submission and Approval Certification

This project report is submitted for partial fulfillment of the Senior Design course describing the design and implementation of our project. We certify that this is an accurate Final Report and we are in agreement that this report is an accurate representation of the Project.

Name	Signature	Date

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I certify that this report is an accurate representation of the Project and I approve it.

Advisor's Name	Signature	Date

Acknowledgements

First and foremost, we would like to thank to our professor Dr. Charles Kim for his help and for his direction with this project. We would also like to thank Dr. Gray Harris for providing us with generous financial support and valuable insight to complete this project. Also, we would like to the Department of Electrical & Computer Engineering for also providing funding and putting together the ECE Day event. Finally, we would like to thank our senior design classmates for giving us helpful ideas and moral support.

Executive Summary

The goal of this project was to design a swallowable capsule for use as an endoscopic device. The capsule contains multiple sensors that collect data and sends data to a receiver as it passes GI tract system. The device had certain design requirements that had to be satisfied. Our group designed a schematic and PCB layout for manufacturing and also used a pre-fabricated board with a microprocessor to act as the capsule. The processor used the Bluetooth Low Energy protocol to transfer data to an iPhone receiver. An application was developed on the receiver that downloads the sensor data. In the end, the focus of the group landed on the temperature sensor aspect of the design. This was done due to time limitations. The performance was quite satisfactory with accurate readings and better precision that required.

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1. Introduction

The aim of this project was to improve upon current designs of swallowable capsules. These are devices that help doctors in diagnosing internal injuries and diseases in the human body. Annually, over 3 million people in the U.S. alone suffer from gastrointestinal (GI) disease serious enough to require hospitalization[1]. Despite new technologies such as endoscopic devices that are used inside the body, much of the GI tract's inner workings remain a mystery. Swallowable capsules are devices that may help in this situation. These devices are swallowed like oral drug pills and contain sensors and circuits that provide data of its surroundings as it travels through the esophagus, stomach, intestines, colon, and rectum of the human body.[1]

The scope of this problem will be to address the physical size of the swallowable capsule. Currently, these devices range in size from 20 to 30mm in length. While this size may be manageable, patients would find smaller pills much easier to swallow. In addition the smaller pill would be less likely to cause blockages as it passes through the GI tract. The device should provide a several pieces of information about the GI tract in real time, including the temperature, pH level, and pressure. The primary function of the capsule would be to provide video of the passage.

2. Problem Formulation & Current Status of Art

The proposition to use swallowable capsules has existed since 1957; however it was not until the 1990s, with the growth of the semiconductor industry, that this technology blossomed.

Olympus Optical is a global image and optics corporation. Their *Endo Capsule* is a swallowable capsule that takes high-resolution images and transmits them to a receiver that the patient has to wear. Images are transferred at up to two frames per second. This device is primarily focused on imaging and does not provide any additional temperature, acidity, or pressure data. The system is described as easy to use. The doctor can monitor the transmitted images from the capsule using a handheld viewer. The capsule has a battery life of 8 hours. It is 11 mm in diameter and 26 mm in length.[2]

SmartPill Corporation has developed a *SmartPill pH.p* capsule. This device is made for one time usage. It measures temperature, pressure, and acidity levels at varying time intervals. After the first 24 hours of operation, the sampling rate decreases as the capsule nears the end of its journey. The capsule has a battery life of 5 days. It is 13 mm in diameter and 26 mm in length.[3]

One of the most experienced companies studying gastrointestinal health is *Given Imaging*. They have two devices, the *PillCam ESO* and *PillCam SB*, that are used for endoscopies of the esophagus and small bowel, respectively.[4] The *SB* version is designed to last for 8 hours, taking 2 images per second for a total of 50,000 images over its total lifetime. The *ESO* takes 14 images per second to produce 2,600 images in total during a 20 minute procedure. The images in both cases are transmitted to a receiver worn around the patients waist. The data is then downloaded from the receiver to a workstation for study by the doctor.

These three manufacturers have products that provide similar functionality to one another. *Olympus* and *Given Imaging* focus on taking visual records of the passage while *SmartPill* focuses on environmental data. None of them actually provide both visual and environmental functionality in one capsule.

In addition, all of these products are slightly too large for the given design requirements. Therefore, the proposed design would need to combine the features of each of these products into a single compact device.

2.1 Available Technology

The swallowable capsule system can be divided up into three main components: 1) the capsule containing sensors that collect data, 2) a receiver that collects data that is transmitted out from the capsule as it passes through the GI tract, 3) a workstation or computer that is used to analyze the data.

Telemetry

With this in mind, the capsule would need to have some kind of transmitting hardware on board, in addition to the sensors. In the current products in the market, a radio frequency (RF) emitter is used. The basic designs use an Analog-to-Digital converter to produce digital data that is then modulated and transmitted on a frequency band such as the Medical Implant Communication Service at 402-405 MHz, as defined by the FCC.[1] The transmission power would need to be strong enough to produce a reliable link to the receiver while also minimizing interference with other devices.

Some products use commercially available RF chips, while other manufacturers use custom-built chips designed specifically for their product. An example of the latter is Given Imaging's PillCams. This specific chip has a data rate of 2.7 Mbps while consuming 5.2 mW of power.[5] Other chips try to incorporate the popular ZigBee protocol which uses the IEEE 802.15.4 standard. The ZigBee specification is designed for applications that require a low data rate, long battery life, and secure networking. The data rate is specified at 250 kbps which is adequate for simple data transmission, but may be too low for rapid image transfers.

Localization

An important requirement is the need to know the location of the capsule at all times so that data is location-specific, that is, an image has a location stamp that allows the physician to know what part of the GI tract it came from. Methods used for this include RF triangulation, magnetic tracking, and computer vision.[5] RF tracking involves using an array of receivers to measure signal strength at multiple points and using the information to estimate the distance traveled. In magnetic tracking, a permanent magnet inside the capsule is detected by a magnetoresistive sensor array using magnetic field strength and direction. This method has proven to be fairly accurate with an average position error of 3.3 mm. The computer vision approach actually looks at the images taken from a camera on-board the capsule. Visual features in the image, vector quantization, principal component analysis, and neural networks are used to classify images as belonging to the upper or lower GI tract.

2.2 Problem Definition

Based on the state of the current endoscopic market, our problem was formalized as follows:

To design a compact, swallowable capsule that provides images, temperature, and acidity data in one unit. The goal is to have the data to be sent to a doctor for later analysis.

3. Design Requirements

The capsule must meet a number of performance requirements. Firstly, the device to be ingested must be no more than 9 mm in diameter, and 23 mm in length. The device must measure temperature, and acidity levels through the whole length of its passage from the esophagus to the colon. The temperature recordings must be measured to an accuracy of ±0.5°C, pH to within ±0.28, and pressure to within ±3.6 mmHg. The device must be able to operate continuously for at least 8 hours. These measurements must be accessible in real-time and should also be available after the procedure in a format viewable on a normal computer. Images of the inside of the GI tract should be transmitted in real-time at a minimum transmission rate of 2 fps. The temperature readings should be transmitted every 15 seconds. The acidity measurements should be transmitted every 2 seconds. The capsule is intended to be disposable, and therefore should be fairly cheap to manufacture. It is also obviously important that the device does not cause any harm to the patient and should be deemed safe for ingestion.

The data requirements are summarized in the following table:

Sensor	Time interval (s)	Precision /Quality
Temperature	15	± 0.5°C
Pressure	5	± 3.6 mmHg
Acidity	2	± 0.28
Image	0.5	QVGA

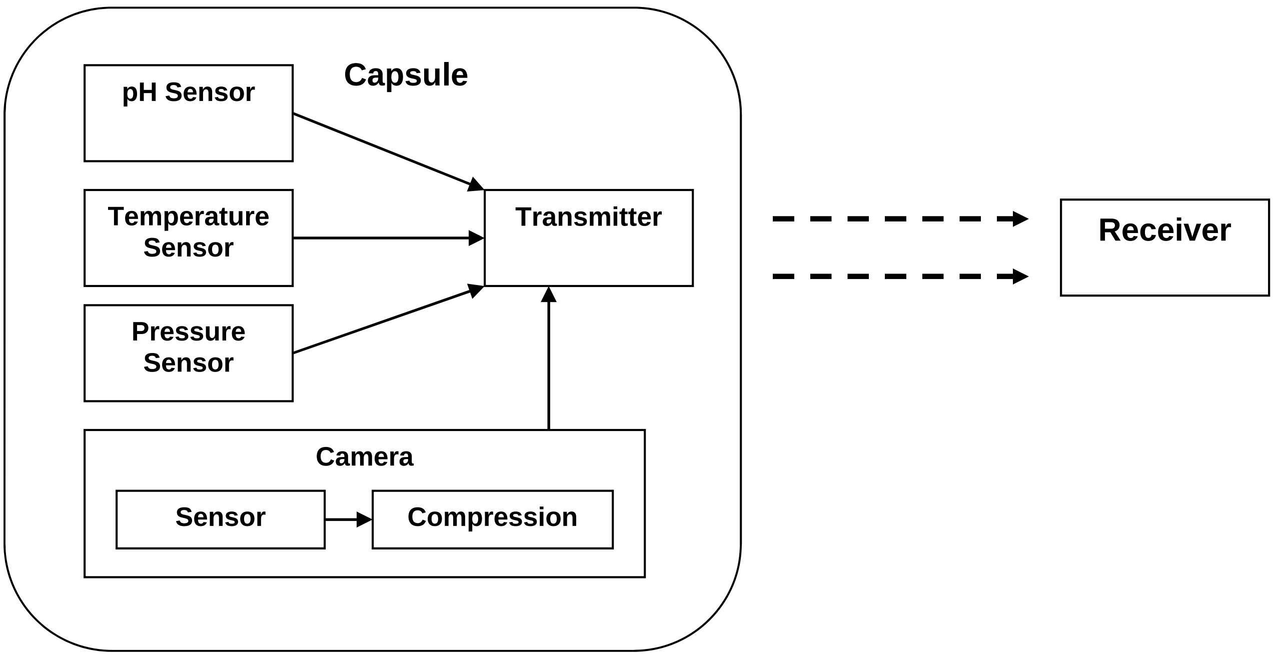
Since this device is to be ingested into the body, approval from the Food & Drug Administration (FDA) is required. The capsules must undergo material-toxicity and reliability tests to make sure that they do not cause harm when ingested.[1] If the device is to use wireless transmission, it must also comply with any applicable Federal Communications Commission (FCC) regulations.

Updated Goals

Our initial goal was to incorporate three sensors in one capsule as defined in our Project Proposal (December 2011). However, due to time constraints and the intention to be able to produce a working product by April 2012, our design goals were updated. Instead of the camera, pH, pressure, and temperature readings, the goal of the project was now to focus on providing temperature readings.

4. Solution Generation

The complete system will consist of two parts: a capsule that collects and transmits data, and a receiver that downloads the data for storage. The data flow diagram is shown as follows:



4.1 Capsule

The device will make use of multiple on-board sensors to collect environmental data. To minimize size, the capsule itself will house only the relevant sensors, camera, and transmitter. The capsule design is designed around minimizing its processing and storage burden in order to reduce the number of its required components, and thus size.

In order to transmit images efficiently over the proposed telemetry link, the images from the camera must be compressed on-board the capsule before transmission. There are several image compression algorithms that are widely used. One such method utilizes a prediction algorithm along with demosaicking, and color transformation has been described by Turgis and Puers[6]. With this method, a 4 mm^2

chip consuming 7.5 mW for compression was developed. The images are then obtained by the receiver and stored.

There will be three sensors that will automatically begin to capture data. The pH sensor will start to obtain data immediately upon activation of the capsule. The pressure sensor will measure the fluid pressure of the pill's surroundings. The temperature sensor will obtain the ambient temperature of the pill's surroundings. These three sensors will provide read-only information. They will provide a constant flow of data that will be processed continuously. This capsule will not have any closed-loop feedback as this is not necessary.

The three sensors will provide analog data that will be sent to the on-board processor. There were three possible options for the microprocessor. The first option was the Ember EM250. This processor provides a ZigBee System-on-Chip that combines a 2.4GHz IEEE 802.15.4 compliant radio transceiver with a 16-bit microprocessor. It has the ability to send data at a maximum rate of 250 Kbps. It can be implemented in a capsule technology because it has 7mm x 7mm dimension. The major downside about EM 250 is that the cost of the development kit is over $2000.

The second choice was Texas Instruments CC2540. The CC2540 is a cost-effective, low-power, true system-on-chip (SoC) for Bluetooth low energy applications. The CC2540 combines an RF transceiver with an industry-standard enhanced 8051 MCU, in-system programmable flash memory, 8-KB RAM, and many other supporting features. The CC2540 is suitable for systems where very low power consumption is required. Very low-power sleep modes are available. Short transition times between operating modes further enable low power consumption. It has dimensions of 6mm x

6mm. The downside to the CC2540 is that it would required the IAR Embedded Workbench to program the microprocessor. Licenses for this software can run up to $4000.

The third option was Nordic nRF8001. The Nordic Semiconductor nRF8001 is an integrated single-chip Bluetooth Low Energy (BLE) connectivity IC that integrates a fully compliant Bluetooth v4.0 low energy radio, link layer, and host stack. The nRF8001 is specifically designed for Bluetooth Low Energy applications. It uses simple serial interface (ACI) supporting a range of different external application microcontrollers. The chip also integrates two voltage regulators, a linear voltage regulator providing a 1.9 to 3.6V supply range, and a DC/DC voltage regulator that when enabled can further cut current consumption by up to 20% when running from a 3V battery cell. The nRF8001 is available in a 32-pin 5 x 5mm QFN package. It has the ability to send 1Mbps data file. The downside to the nRF8001 is that its development kit is quite expensive.

In order to analyze the cost and benefits of each option, a decision matrix was created. The table below displays the cost analysis study.

Criteria	Weight	TI CC2540		Nordic nRF8001		Ember EM250	
Cost	35	4	1.4	3	1.05	2	0.7
Programming	30	3	0.9	3	0.9	3	0.9
Receiver	10	2	0.2	2	0.2	4	0.4
Data Rate	25	3	0.75	3	0.75	2	0.5
Weighted Total		3.25		2.9		2.5	
Rank		1		2		3	

As can be seen, the cheaper price of the TI CC2540 solution was the deciding factor in its selection. Both the CC2540 and nRF8001 use BLE as opposed to the Zigbee protocol used by the EM250, and this provides data rate advantages. The development kit for the CC2540 was also much cheaper in comparison to the other two options and so this microprocessor was chosen for this project.

4.2 Receiver

This device would be designed to be worn by the patient around the waist. It contains an array of antennae that communicates with the transmitter in the capsule. The receiver will have to be worn by the patient for 8 hours and returned to the doctor's office. The doctor would then download all the data from the receiver for analysis. There are two approaches to implementing the receiver. One is to build a receiver by combining several different parts. This would involve flash memory for storage, and a microprocessor for computation, and a transceiver and antenna for communication. It would also need an interface such as USB or serial interfaces in order to take the data to a doctor. The main issue with this approach is the obvious complexity in creating such a device, especially in the short time period that we have. However, this plan would afford more flexibility to design a device that better fits our needs.

The second option would be to use an existing device such as a Smartphone. With the choice of the CC2540, the Smartphone would need to be Bluetooth 4.0 compliant. One of the major devices on the market is in fact Apple's iPhone 4S. This device allows for the development of a software application that can access the BLE functionality of the phone that is required. The benefit of this approach is the ability to create an application very quickly, due to the availability of numerous resources and guides. However, the main drawback of this plan is the cost of the iPhone 4S. Using a widely available device such as the iPhone also has the benefit of making the entire design more flexible. Patients would be able to use their own devices to sync with the capsule by simply downloading an application. This would bring down overall costs tremendously. As a result, the option to use the iPhone 4S was deemed a better choice compared to fabricating a device from scratch. While cost would be an issue, our team was able to procure the device for use in this project.

5. Implementation

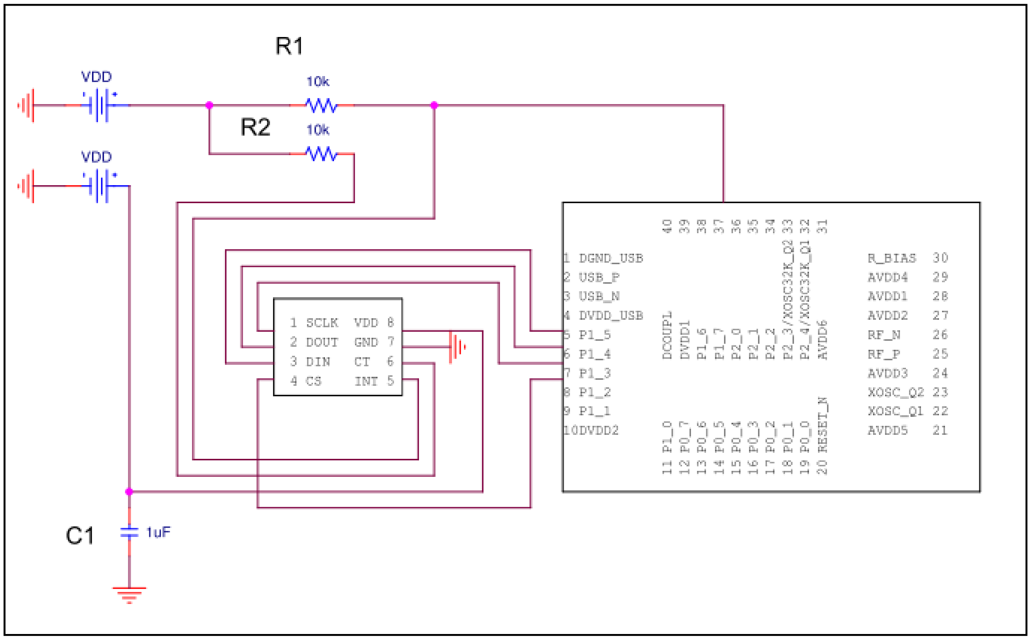
5.1 Capsule

Primary Plan

Following through on Plan A, a circuit consisting of the CC2540 microprocessor, and ADT7310 temperature sensor was created. Using a Keyfob design created by Texas Instruments in their Mini Development Kit[7], a schematic was created in OrCAD PSpice.

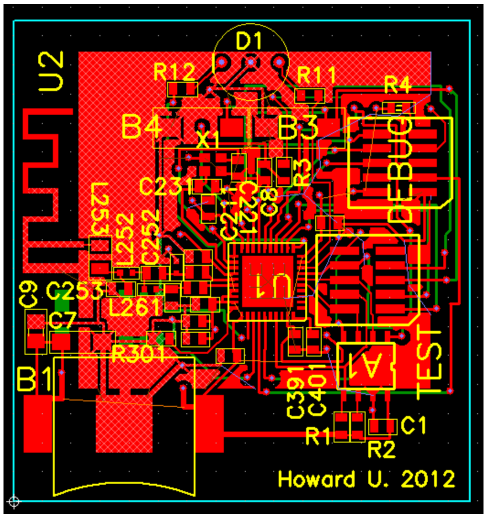
The TI Keyfob design included an accelerometer, the CMA3000, which also followed the SPI interface found on the ADT7310. So in the actual schematic, the CMA3000 was substituted in for the ADT7310 and the connections between the accelerometer and the CC2540 were used as guide when wiring the temperature sensor. The resulting schematic diagram is shown in Figure 5.1.

Figure 5.1 – Circuit Schematic of Temperature Sensor and Microprocessor



The schematic was then placed into a PCB layout. The software that was used was Pad2Pad's proprietary layout software. A netlist was first created using all the required components and an auto-route was performed. This creates a preliminary arc layout based on certain constraints such as arc spacing and width. Then the rest of the net connections were traced out manually. This was a fairly time-consuming task because the size of the board was quite small and the components were densely packed. Figure 5.2 shows the resulting PCB layout.

Figure 5.2 – PCB Layout using Pad2Pad Software



Several different components were used, as required by our circuit schematic. While Pad2Pad had a list of its stocked components, these parts were seen to be too large for our design. So, the components were chosen based on their availability from Digikey, an online electronics component distributor. Due to this restriction, components of different sizes had to be used. Footprints ranged from 1005 to 3216 (metric) packages. A meandered inverted F antenna was used based on a design by Texas Instruments.

The design was then sent to Pad2Pad for manufacturing and assembly. In the meantime further work was done on our secondary plan which involved using a PCB board with the microprocessor already attached. This idea stemmed from the fact that the CC2540 has a built-in temperature sensor.

Implementation Update

The assembled device was returned to our team in Mid-March 2012. From the outset, we were unable to flash the microprocessor memory on the device. We performed several checks of the components and arc layout with satisfactory results. One possible source of error was the use of the CC Debugger. This is a device that acts as an interface between the computer with the program code, and the PCB. There is suspicion that the debugger's own flash program may be preventing communication with the CC2540 on our PCB. However, due to the lack of time available for troubleshooting, our group decided to fall back on a secondary plan.

Secondary Plan

In this path, the idea was to use a pre-fabricated board that has the CC2540 microprocessor already assembled. The goal was to use a built-in temperature sensor found within the CC2540 for temperature measurement instead of the external temperature sensor. The board used in this plan was the CC2540 Mini-Development Keyfob. The overall requirement in order to activate and read from the temperature sensor in the device was to change and set certain registers in the CC2450. Two of them included the TR0.ADCTM and ATEST.ATESTCTRL registers. These had to be set such that one of the input channels to the Analog-to-Digital Converter (ADC) on the CC2540 was coming from the temperature sensor.

Once the proper voltage in degrees Celsius was obtained, the value had to be converted to an 8-bit integer. This initially made temperature readings somewhat coarse because the values would be rounded to an integer value. In order to make readings more precise, the range of temperature values provided by the capsule was reduced.

The range was set to allow for values between 24.2°C to 49.8°C. This allowed for readings with a precision of 0.1°C.

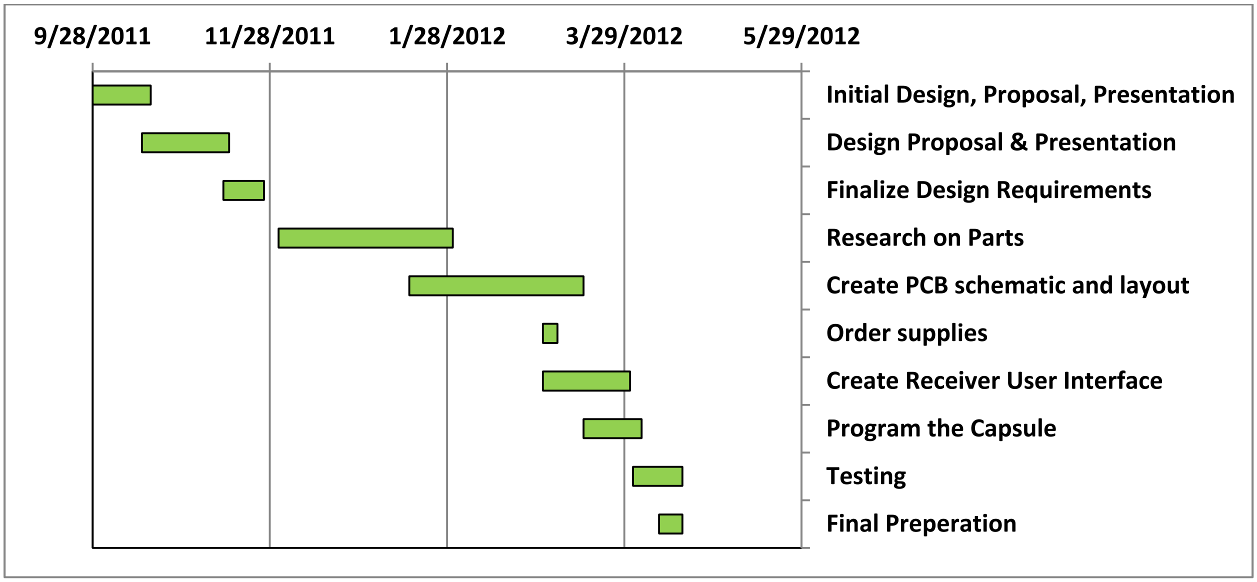
5.2 Receiver

The system's receiver was based around the iPhone 4S smartphone manufactured by Apple Inc. A software application was created to perform the required tasks of connecting to the capsule, downloading the sensor readings, storing the readings, and sending them out via email. The most important aspect was the BLE connectivity. The iPhone SDK contains the CoreBluetooth framework which is a library made for handling BLE connections. Since the programming language used was Objective C, several objects or classes were made to run the program. Two important ones were the capsuleSensor, and MainViewController classes.

The capsuleSensor essentially acted as a representation of the actual swallowable capsule. Any type of communication between the capsule and the iPhone would thus be initiated or handled in this class. This included functions to get list available services advertised by the capsule, read and write values for BLE attributes, and notify of successful connections. The MainViewController was the primary user interface. It listened for notifications from capsuleSensor, sent requests to connect and disconnect the BLE connection, saved the temperature readings to a text file, and handled connection timers.

Overall, the project spanned most of the Fall 2011 and Spring 2012 semesters while the bulk of the work was done since February 2012. A timeline of the project progress is shown in Figure 5.3.

Figure 5.3 – Timeline of Project Progress



6. Performance Analysis & Evaluation

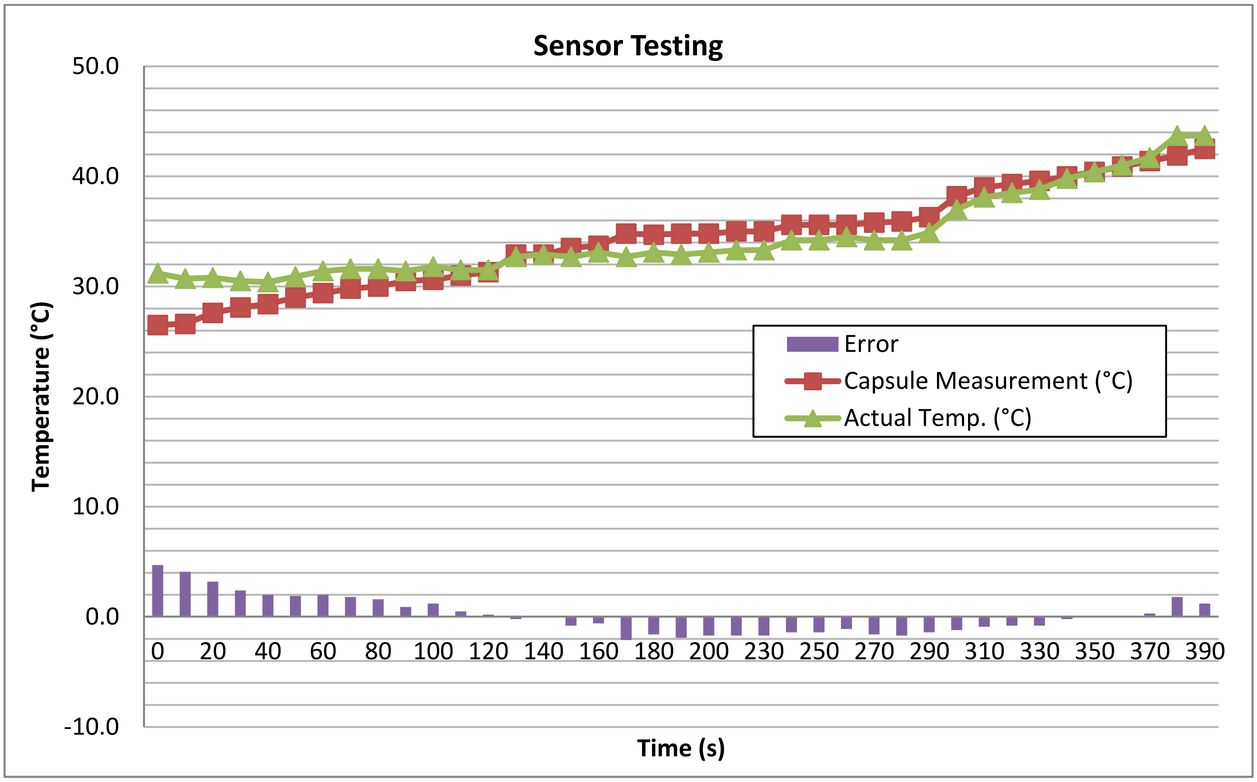
6.1 Testing Scheme

A test environment was created in order to evaluate the performance of the system. Since the design is based on accuracy of the temperature sensor, the capsule was subject to a range of temperatures with an active connection to the receiver. As a benchmark, the 'actual' temperature of the capsule was measured using a non-contact Infrared (IR) thermometer. In order to obtain low temperatures, the capsule was placed in a household refrigerator. In order to obtain higher temperatures, the capsule was heated using a hair blowdryer.

6.2 Results

Based on the aforementioned testing scheme, measurements were taken and the results are shown in Figure 6.1.

Figure 6.1 – Plot of Measurement Results



As can be seen, the capsule measurement generally follows the trend of the actual temperature. This is especially the case for temperatures above 30°C. A figure also displays the error in the readings at each interval. As can be seen, the error is fairly significant early on but drops down in magnitude. The average of the magnitude of error was found to be 1.4°C, with a maximum of 4.7°C and a minimum of 0.0°C.

The system allows for temperature reading intervals of 1s, with the option for 2, 3, or 15 second intervals. The size of the final capsule was 4 cm in width by 5 cm in height. The battery life was found to be longer than 8 hours.

6.3 Evaluation

The following table summarizes the performance of the system when compared to the design requirements set out in Section 3.

Requirement	Current Status	Outcome
Temperature Precision	Obtained readings of ±0.1°C	✔
Temperature Reading Rate (1/15 Hz)	Can go up to 1 Hz	✔
Camera	No camera module	
pH Sensor	No pH module	
Size (0.9 x 2.3 cm)	Current size is 4 x 5 cm	
Battery Life	+8 hours	✔

As can be seen, the requirements related to temperature sensing were largely met. The system successfully measures temperature and transmits the data to a receiver, with satisfactory precision, and speed. Due largely to the choice in transceiver protocol, we were able to also achieve the battery life requirement of 8 hours. However, the size of the final capsule was larger than the requirement that was based upon regulatory requirements. In addition, the original goal of incorporating a camera and pH sensor into the capsule still needs to be done.

6.4 Resources & Budget

The following table outlines the final budget for the project.

Item	Cost		
	Schedule A	Schedule B	Schedule C
iPhone 4S	$ 710	$ 199 ($ 710)	-
CC2540 Board	$ 101	$ 101	$ 101
Batteries	$ 5	$ 5	$ 5
PCB Fabrication	$ 700	-	-
Electrical Parts	$ 100	-	-

ADT7310 Kit	$ 90	-	-
IR Temp. Sensor	$ 30	$ 30	-
Health Thermometer	$ 5.00	$ 5	-
Ice Pack	$ 4.00	-	-
Apple OSX	$ 30.00	-	-
Total	**$1,775**	**$ 340 ($ 851)**	**$ 106**

Schedule A outlines the cost of all items spent on the project. Schedule B outlines the cost of the items that were used for the final prototype. Schedule C outlines the cost of the capsule itself. The idea behind the system is that the capsule is the main piece that would be provided by the doctor while the receiver could be supplied by the patient. Any smartphone with Bluetooth 4.0 support could in theory be used in place of the iPhone receiver that was used in this case.

7. Conclusion

A swallow able capsule is a safer and cheaper alternative to that of traditional methods for determining intestinal diseases; one procedure being endoscopies. It is a tool that can provide critical information about the GI tract without harming the patient. The initial design of the project was to incorporate the use of various functions into one capsule. However, the project successfully implemented the use of one function; the temperature sensor. With this temperature sensor readings with an accuracy of 0.1 were obtained and transmitted to the receiver. On the receiver side, the application was able to display the temperature, position of the sensor, time, date, as well as save and email these values for further use. Over an 8 month period a timeline was adhered to as a tool for better execution of the project. This timeline laid out guidelines for productivity as well as the roles of each member within the team as it applied to different areas of the project. The timeline included design proposal and approval, research time, design and building, as well as testing. In order to design and build the project it is imperative to have an understanding of microprocessors, coding and Bluetooth. IAR workbench was utilized in programming the microprocessor and Xcode through Apple was utilized in creating the application for the receiver. The testing environments were used in order to evaluate the performance of the sensor when compared to the design requirements and make corrections when necessary. In doing so, the design requirements were met. Overall, the total cost for the project was $1,775 which included the hardware and software applications of the entire project. A majority of that cost was handled by Dr. Gary Harris in the department of Nanotechnology at Howard University who was the advisor for the project.

8. Recommendations

There are several recommendations for future work that can be applied to this project.

1. PCB Design and Schematic – It is important to make sure that the correct connections within the schematic are made in designing the board. It was observed that the PCB was not connecting to the external sensor. In addition, using both sides of the PCB board would scale the project down to a smaller size. The PCB board contained all the components necessary for the project and is an easier tool for implementation of the project.

2. It would be useful to have a capsule casing that is both waterproof and sensitive to any change in temperature. Some type biocompatible material that will not harm the human body while refraining from damaging the sensor itself. This would allow for a real world model of what the completed swallow-able capsule would look like on a larger scale.

3. No other swallowable capsule technology incorporates various functions such as PH and camera into one unit. Working towards implementing all into one poses challenges but would be a beneficial focus.

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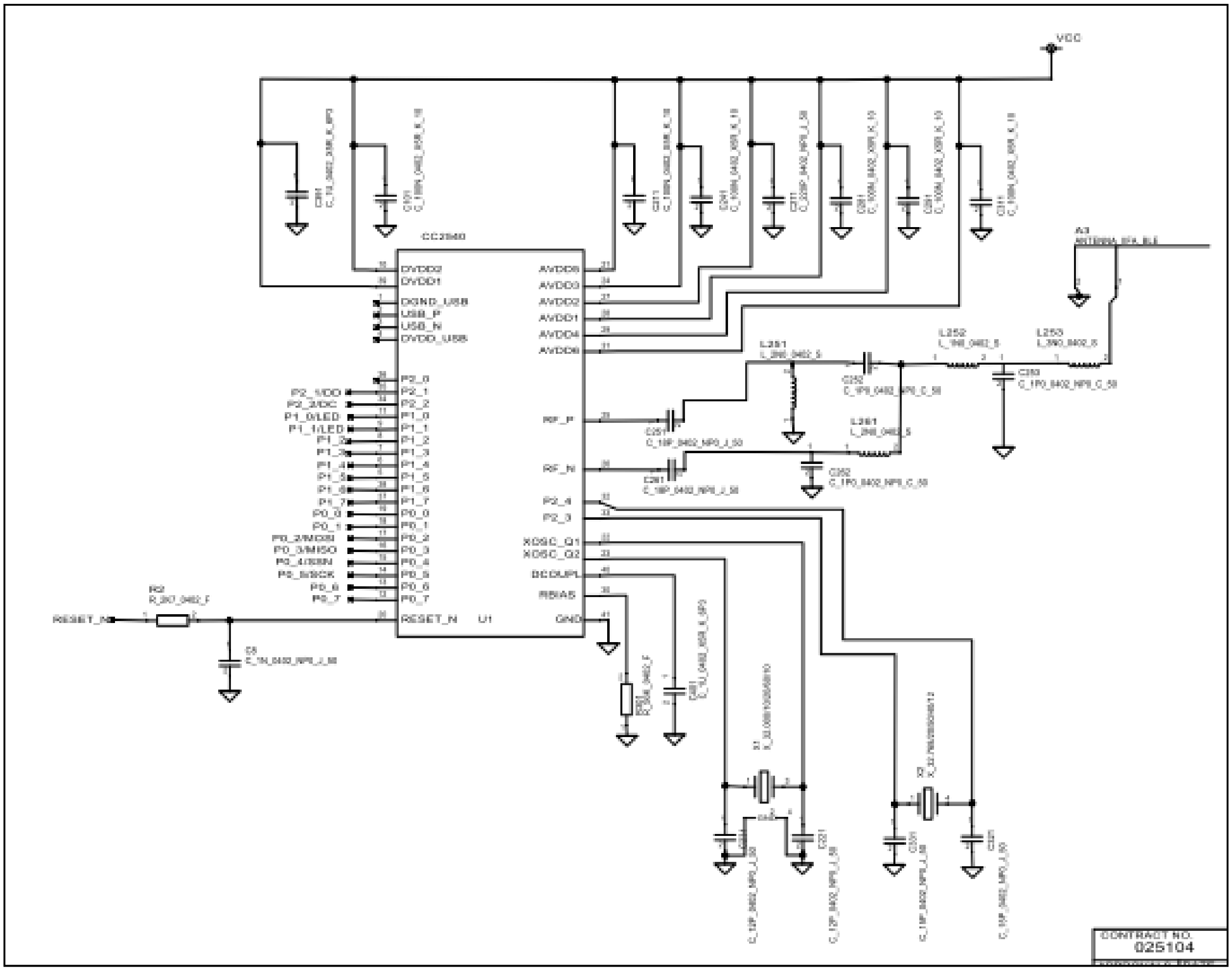
[7] D. Turgis, R. Puers, Image compression in video radio transmission for capsule endoscopy, Sensors and Actuators A: Physical, Volumes 123-124, 23 September 2005, Pages 129-136, ISSN 0924-4247, 10.1016/j.sna.2005.05.016. (http://www.sciencedirect.com/science/article/pii/S0924424705003456)

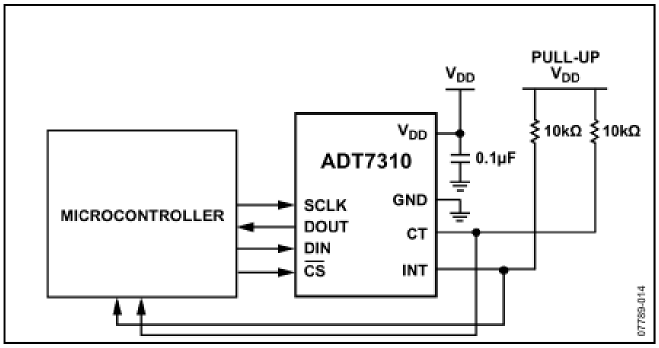
Appendix

TI Keyfob Schematic



Source: CC2540_Keyfob_Schematic, Texas Instruments, 2011

ADT7310 Temperature Sensor Schematic



Source: ADT7310 Datasheet, Analog Devices, 2011