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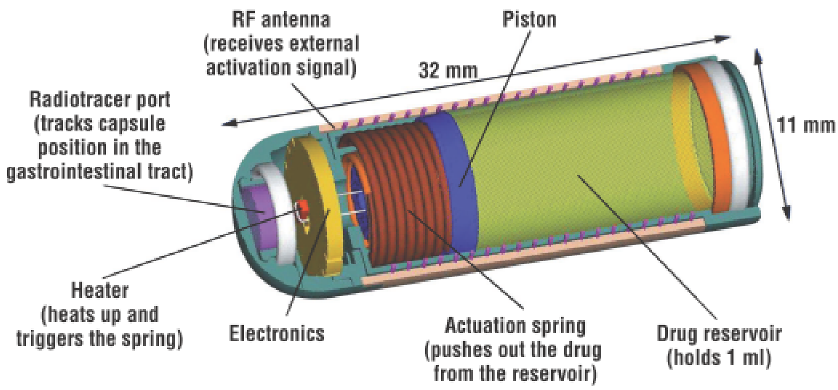

Senior Design Project:

Swallowable Capsule II: Final Proposal

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1. Introduction

1.1 Objective of the project

The aim of this proposal is to suggest an improvement to current designs of swallowable capsules. The main focus will be to miniaturize the device.[1]

1.2 Background of the project

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

2.1 Problem definition

Design a compact, swallowable capsule that provides images, temperature, and acidity data in one unit.

2.2 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 ±1°C, and pH to within ±0.5. The device must be able to operate continuously for at least 8 hours. These measurements must be accessibly in real-time to a doctor using 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.

2.3 Compliance

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.

3. 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.

3.1 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.

3.1.1 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.

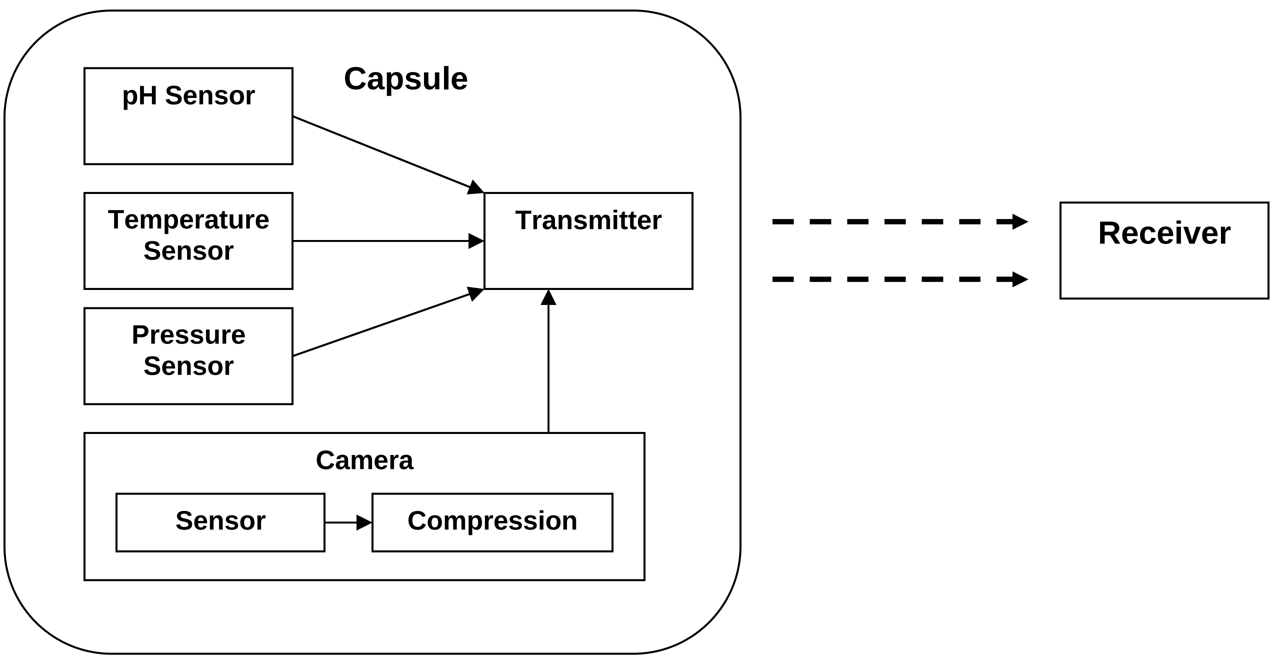
3.1.2 Localization

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.

4. Solution Approach

4.1 Primary Solution

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:



4.1.1 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 are two proposed processors to be used, the EM-250 ZigBee, and CC2540 Bluetooth Low Energy. The EM-250 follows the 802.156.4 IEEE standard and operates at the 2.4 Ghz range. It contains a built-in Analog-to-Digital (AD) converter. The ZigBee will then transmit the sensor data and the images to the receiver. The CC2540 operates on the new Bluetooth Low Energy (BLE) protocol. This processor also contains a built-in A/D convertor. The transmitter will be unidirectional; data will be transmitted from the capsule to the receiver only.

4.1.2 Receiver

This device is 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 continuously obtain data from the capsule and store it locally on flash memory. The receiver will contain a microprocessor and local memory, much like a regular Smartphone. It will also have a USB 2.0 interface. It will be designed to clip onto the patients belt or pants.

The patient will be wearing the receiver belt prior to swallowing the capsule. Once the procedure has been overseen by the physician, the patient is allowed to leave. 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.

4.2 Scenario Considerations

1. Receiver loses connectivity with the capsule

   There are a number of scenarios where the receiver could lose connectivity with the capsule. Firstly, the patient may remove the receiver from his/her person and forget to put it back on. Secondly, the signal from the capsule may be lost due to interference. If the capsule runs out of power before the entire process is complete, the receiver would also lose connectivity. In each of these cases, the receiver will contain an incomplete record of the endoscopy. When the data is analyzed by the physician, the discrepancy would be noted, and if the lost information was important, another procedure could be undertaken.

2. One or more of the sensors malfunctions
   If one of the sensors malfunctions, the data record in the receiver would show this problem. There would be no input signal to the A/D converter from that sensor, and therefore the measurements from the sensor would not be transmitted.

4.3 Testing and Verification Plan

A prototype will be built using off the shelf sensors and available telemetry chips as proof of concept. The devices will be tested and improved.

4.4 Alternative Solutions

1. Handheld Data Analyzer

Instead of a fixed receiver worn by the patient, a handheld device could be used by the doctor to see captured data in real-time. This would allow for a quicker operation, but would be limited in the type of data that the system provides. The capsule takes time to traverse through the GI tract and so this approach would only be feasible for imaging of the upper GI tract.

5. Tasks and Deliverables

5.1 Tasks

Each group member will be tasked with understanding a certain part of the system. Group member 1 will study the function of the temperature, pH, and pressure sensors. Group member 2 will focus on the camera and image processing. The third group member will focus on telemetry and the receiver. With these specializations, the group as a whole is expected to operate more productively.

5.2 Deliverables

We expect to have a working prototype of the device by the end of March 2012. The device is expected to record and transmit temperature, pH, and pressure data. The device is also expected to transmit images for storage.

6. Project Management

6.1 Timeline & Milestones

Milestone	Scheduled Date
Initial Proposal	September 28, 2011
Written Proposals: Version I	October 4, 2011
Written Proposals: Version II	October 12, 2011
Final Proposal Presentation	October 2011
Evaluation/Selection of Design	October 2011

Milestone	**Scheduled Date**
Final Proposal Presentation December	November 2011
Evaluation/Selection of Design	November 2011
Final Written Proposal	November 2011
Peer Evaluations	November 2011
Finalize Design	December 2011
Ordering of components/Parts	January 14, 2011
Commencement of the development of the design	February 2012
Create testing environment	February 2012
Completion of project prototype	March 2012
Testing of project	March 2012
Documentation of project	April 2012
Prepare presentation slides	April 2012
Project presentation on ECE Day	April 2012

6.2 Resources & Budget

Component	**Unit Price**	**Quantity**	**Total Cost**
Temperature Sensor	$20.00	1	$20.00
Acidity Sensor	$50.00	1	$50.00
Camera	$20.00	1	$20.00
Microprocessor	$200.00	1	$200.00
Battery	$2.00	5	$10.00
Receiver	$50.00	1	$50.00
Miscellaneous	$50.00	1	$50.00
Manufacturing	$250.00	1	$250.00
		Total	**$650.00**

7. Conclusion

A swallowable capsule is an alternative to traditional endoscopic procedures. They can provide vital information about the condition of the GI tract without any complicated invasive procedures. The problem at hand is to incorporate the separate functions of existing products into one device. The primary solution was based upon using the capsule only as a recording and transmitting device. A receiver would continuously download the data for later analysis.

The capsule is designed to be a disposable device. The cost of the capsule is based on estimates of the costs of the individual sensors and so may change as more useful sensors are found. By March 2012, we expect to have a prototype of the device. The system would be expected to provide similar functionality as the final design of the system.

8. References

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