Data Acquisition Implant

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1.0 INTRODUCTION

The purpose of this document is to describe the engineering challenge of creating a battery-less implant in a rat that is capable of wirelessly transmitting data that is collected through sensors. Such a system can address a variety of needs. For this project, we will limit our project scope to applications of animal testing. Specifically, we will address testing by the FARMA drug companies. Because this system is low cost, researchers can use the sensors in this device to gather more accurate data from animals and ultimately improve drug cost and effectiveness. Our team plans to implement this design during EE 464 in the fall semester of 2016. In order for our design to meet the needs of the client, we have developed a set of requirements and constraints. User inputs consist of data requests, while system inputs consist of the sensor data. User outputs include raw data, while device outputs include the data associated with each sensor. Finally, our system must uphold certain performance standards regarding input ranges and accuracy.

2.0 DESCRIPTION OF THE DESIGN PROBLEM

The main goal of this project is to develop an embedded system that can be implanted in a laboratory animal, collect data, and wirelessly transmit the data to the researcher. This device will be used in a laboratory environment where animals are used to test the effects of various drugs. The device will monitor the animal for special conditions, ~~once it has been implanted,~~ allowing researchers to focus on analyzing the data rather than collecting it.

2.1 Problem Background

When products are in development, they reach a phase in which they need to be tested for correct functionality. There have been many terrible incidents where drugs were allowed to be sent to consumers without being tested, which led to disastrous results. [1] However, many products are not allowed to be tested on humans due to legal and health reasons. Therefore the 1938 Federal Food, Drug, and Cosmetic Act was passed requiring drugs be tested on animals before being marketed. [1]

However, monitoring the test animals for specific measurements can be difficult due to the quantity of animals being tested on during an experiment. ~~So the idea of~~ an implant that will take the desired measurements of the test subject and report them to the researcher is an ideal solution. This implant would connect to necessary sensors and collect the desired data. Then the

implant would relay this information to the researcher at their request. However, there are also many challenges with this idea. Due to the implanted nature of the system, a battery powered system would not be ideal since switching batteries would be difficult. In addition, a connection from the system to the researcher would have to be wireless. Therefore, the goal of this project is to create a battery-less implantable embedded system that can take in sensor data and wirelessly transmit it to the researcher.

2.2 Stakeholder Needs Analysis

The primary stakeholder in this project would be a pharmaceutical company that does drug testing on animals. They are looking for a cost effective solution that is adaptable to the desired environments.

Below is a list that outlines major needs of our system

- I/O pins for sensors
- Battery-less system
- Wireless communication method to transfer data
- Appropriate size for implanting into a rat
- Biocompatibility of materials
- Low cost

2.3 Design Functionality

The system will be in a sleep mode by default. In the event that a user wakes up the system, a wireless communication between the system and user's computer will be established. User will use the computer to control the system implanted in a laboratory rat. Once the connection becomes stable, the user can start acquiring biosignals. Finally, the user can monitor the data through a user interface software created for the system.

2.4 Use Cases

Our system has one use case. Biomedical researchers will implant our system into a laboratory rat to monitor biosignals.

2.5 Ethical Considerations

There are several major ethical concerns that will factor into the design of our system. First, the frequencies at which our device is powered and communicates and the communication protocol it follows needs to adhere to the standards set forth by the Federal Communications Commission (FCC). Second, because our device will be embedded into an animal or a human, our device also needs to comply with the Animal Welfare Act of 1966 (AWA) and the regulations set forth by The Food and Drug Administration (FDA). Finally, as engineers, it is also important that as a team, we, and our device, adhere to the IEEE Code of Ethics.

The FCC has specific regulations describing the available frequencies that our device can use for power and communication as well as the communication protocol that it can use. For example, the only frequency bands that have been designated for use under specified conditions are those between 9 kHz and 275 GHz. In addition, wireless power transfer devices operating at frequencies above 9 kHz are intentional radiators and are subject to Parts 15 and 18 of the FCC rules.

Three major ethical concerns stem from implanting devices into humans. First, it is a possible violation of an individual's right bodily integrity [RFID Inside]. Only those who voluntarily agree to the implant should receive one. Second, it is a possible infringement of an individual's right to privacy. Because the device communicates personal data, it is essential to design a secure system that will safeguard against possible misuse of that data. Finally, implants can pose a possible safety hazard. For example, the implant may migrate under the skin and throughout the body. Additionally, the implant could be a source of interference with other medical technologies and devices.

Finally, as engineers, it is important that we adhere to the IEEE Code of Ethics. It is our responsibility to make decisions "consistent with the safety, health, and welfare of the public" [IEEE Code of Ethics]. In addition, we must "disclose promptly factors that might endanger the public or the environment" [IEEE Code of Ethics].

2.6 Project Deliverables

Our project deliverables consist of a prototype and the associated documentation. The prototype will consist of a main system built around TI MSP430 processor, a cage with induction coils attached to its walls, and a user interface software. The documentation will include both client and user documentation. The client documentation will describe our research and our design while the user documentation will describe the installation, operation, and maintenance of the system.

3.0 DESIGN REQUIREMENTS

To meet the needs of our client, we will develop a two device system. The first device will be an implanted device that will be collecting the data and outputting it when requested. The second device will be a transceiver that has four main functions: providing power to the implanted device, sending commands to the implanted device, receiving the data, and forwarding that data to a computer.

3.1 Inputs and Outputs

Our design takes inputs from two sources and responds with an output of the collected data. Inputs are received from the user as well as the sensors on the implant. User inputs consist of powering the transceiver and the chosen commands for getting the output. Sensor inputs consist of measurement data of the laboratory animal collected by the sensor. The system will output the data measured to the user in an easy to read format. Figure 1 below depicts the inputs and outputs of our design.
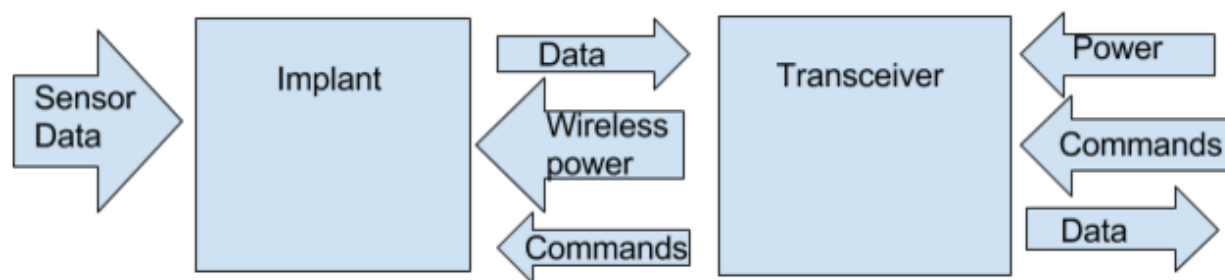

Figure 1. Input and Output Diagram

3.1.1 *Input Specifications*

For our design, inputs will come in from the sensors and user. The implant will take inputs of power and commands from the transceiver, and input of measurement data from the sensors. Table 1 describes the implant input specifications. The transceiver will take in inputs of power and commands from the user, and the sensor data from the implant. Table 2 outlines the transceiver input specifications.

Table 1. Implant Input Specifications

Title	Description
Wireless Power	The device has no battery, therefore must be powered wireless via magnetic fields.
Commands	The transceiver can make specific requests such as the sensor data or the implant's ID.
Sensor Data	The implant must be able to sample from different sensors such as temperature, acceleration, glucose levels, etc.

Table 2. Transceiver Input Specifications

Title	Description
Power	Needs to be able to power logic and the coils
Data	Data received from the implant such as the sensor data or ID.
Commands	The computer will send commands to the receiver for specific requests to be relayed to the implant.

3.1.2 *Output Specifications*

For our system, the main output will be the sensor data to the user from the transceiver. Additionally, internal outputs include the sensor data from the implant to the transceiver and the outputs of power and commands to the implant from the transceiver. Table 3 & 4 describe the output specifications of the system

Table 3. Implant Output Specifications

Title	Description

Data	When the implant is turned on it will collect data from its sensors and wirelessly communicate them to the transceiver.

Table 4. Transceiver Output Specifications

Title	Description
Wireless Power	The transceiver will deliver power to the implant through large coils on the side of the rat's enclosure.
Commands	The transceiver will transmit the commands from the computer to the implant.
Data	The requested data that was retrieved will get sent to the computer.

3.2 User Interface Specifications

The user interface will be as simple and easy to use as possible. The interface will be a computer application that is connected to the transceiver. The user only needs to press a button, and the system will then ~~automatically~~ power up the implant, sample the data, and display the data to the user.

3.3 Environment Specifications

Because the end goal is to have our device implanted in a rat, there are certain environmental conditions that our device will have to be able to operate under. For example, our device should be able to function correctly despite fluctuations of the internal conditions of the rat. Sterility and Biocompatibility are also necessary to ensure the device does not negatively impact the rat. Table 5 describes the environment specifications.

Table 5. Environment Specifications

Title	Description	Specification
Temperature	Range of temperature that the system needs to operate in	Average Temp = 37.5 C
Water Resistance	How much water the device can withstand	Complete protection

3.4 Performance Specifications

In order to be used as intended, our device must to adhere to certain performance specifications. First, since our device will be implanted into a rat and not easily accessible, out device must be able to last within the rat for a set amount of time. Second, our device will need to meet several hardware specifications, such as memory size, processing and communication speed, and input/output pins, in order to process information and communicate effectively. Table 6 describes the performance specifications.

Table 6. Performance Specifications

Title	Description	Specification
Lifetime	How long the device must be able to function from the time for implantation	At least 6 months
ROM Size	How much Read Only Memory the device must have	At least 2k bytes
RAM Size	How much Random Access Memory the device must have	At least 100 bytes
Processing Speed	How fast the processor must run	128 kHz - 10 MHz
Communication Speed	How fast the device must be able to send and receive data	1 Hz - 10 Hz
I/O Pins	How many input/output pins the device must have	4 - 6 pins
Communication Frequency Range	Frequency in which the device must communicate	Any unrestricted radio band

3.5 Test Criteria

During testing, certain criteria will help us determine the success of our device. These measurements will allow us to ensure that our device is able to meet the previously stated specifications throughout the design process.

- Power delivered by the induction coils
- Incoming communication speed (bandwidth)
- Outgoing communication speed(bandwidth)
- Reliability of communication
- Accuracy of internal measurements

4.0 TEAM QUALIFICATIONS

In order to solve our design problem, our team will need to be experienced with electromagnetism, embedded systems, networking protocols, and circuit design. To power our device, we will use induction coils. These coils will involve electromagnetism and circuit design, both of which Corey, Makeila, Albert, and Michael have experience with. The transmission between the chip and receiver will require networking protocols. This will add a heavy software component, of which Thomas and Anish have experience with. Finally, five of our six team members have primary tech cores in embedded systems, so we can distribute chip design among the team. We will implement this plan during EE 464 in the fall of 2016.

Table 7. Team Qualifications

Team Member	Planned Contributions	Areas of Expertise	Related Course Work
Corey Cormier	Induction coils, PCB design	Embedded Systems	EE 316, 445L, 438, 325
Thomas Ermis	Communication protocol design	Software, Networking	EE 316, 319k, 461L
Albert Marzullo	Induction coils	Embedded Systems	EE 316, 445L, 325
Michael Park	Induction coil design/hardware software Interface	Embedded Systems	EE 445L, 460M, 325
Makeila Sorensen	Circuit Design	Embedded Systems	EE 316, 319k, 438
Anish Vaghasia	Communication protocol design	Embedded Systems	EE 316, 445L

5.0 CONCLUSION

This document describes the design challenges of creating a system that acquires data from a rat. This system will provide accurate data measurements to researchers, who can then use this data to drastically reduce testing costs and improve drug effectiveness. Our clients, the pharmaceutical drug companies, require that our system be small enough to fit within a rat and have various sensors for acquiring data. Our system must also be waterproof, sterile, compatible

with the biology, and have an average temperature threshold. To meet these needs, we have outlined a set of specifications. User inputs consist of specific data requests, while system inputs consist of the sensor data. User outputs include raw data, while device outputs include the data associated with each sensor. Furthermore, our system must adhere to several performance standards regarding processing capabilities, lifetime, and communications. Our next step is to conduct research on potential design solutions so that we can begin the prototyping.

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APPENDIX A – APPLICABLE STANDARDS

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A.1 Federal Communications Commission

"Currently only frequency bands between 9 kHz and 275 GHz have been allocated (*i.e.*, designated for use by one or more terrestrial or space radio communication services or the radio astronomy service under specified conditions)."

"Wireless power transfer devices operating at frequencies above 9 kHz are intentional radiators and are subject to either Part 15 and/or Part 18 of the FCC rules. The specific applicable rule part depends on how the device operates, and if there is communication between the charger and device being charged.

Devices specifically intended for use for wireless power transfer, or inductive charging, require FCC guidance for frequency exposure review. This includes Part 18 devices. The responsible party or manufacturer must seek guidance from the FCC by submitting a wireless charging application inquiry at http://www.fcc.gov/labhelp.

The initial inquiry shall include the following:

    i.   In the "Subject" line, fill the field as follows: Seeking guidance for wireless chargers;

    ii.   complete product description, including coil diameters , number of turns and current;

    iii.   the rule part(s) the device will operate in and the reasoning for rule part(s);

    iv.   planned equipment authorization procedure;

    v.   drawings, illustrations;

    vi.   frequencies;

    vii.   radiated power;

    viii.   operating configurations

    ix.   conditions for human exposure [2], and

Intentional radiators transmitting information must be certified under the appropriate Part 15 rules and will generally require an equipment certification, except for special types of devices meeting requirements under Section 15.201 which are subject to verification. A charger may operate in two different modes: charging and communications. It is possible for the device to be approved under Part 18 for the charging mode and Part 15 for the communications mode, if it can be shown that (1) the device complies with the relevant rule parts and (2) the functions are

independent. Part 18 consumer devices can be either certified or approved under DoC, only after the required SAR guidance has been given (as noted above ". . . by submitting an inquiry at www.fcc.gov/labhelp" . .) and the necessary test requirements have been completed. Finally, it is possible that the power charging function could be approved under Part 15 rather than Part 18 if the device meets all of the requirements of the appropriate Part 15 rule."

A.2 Animal Welfare Act of 1966

"Animal Welfare Act of 1970 P.L. 91-579 renamed the "Laboratory Animal Welfare Act" the Animal Welfare Act and expanded animal coverage to include all warm-blooded animals determined by the Secretary to be used for experimentation or exhibition, except horses not used in research and farm animals used in food and fiber research. The 1970 law also incorporated exhibitors; defined research facilities; and exempted from coverage retail pet stores, agricultural fairs, rodeos, dog and cat shows."

"Title XVII, Subtitle F, of the Food Security Act of 1985 (P.L. 99-198, the omnibus 1985 farm bill). The law directs the Secretary to set new minimum standards of care for handling, housing, feeding, water, sanitation, ventilation, and so forth. One new provision that was highly contentious at the time singles out two species by requiring standards for the exercise of dogs and the psychological well-being of primates. The law provides that research facilities must have procedures that minimize pain and stress to the animals, and describes practices considered to be painful. Each research facility must establish an Institutional Animal Care and Use Committee to review research proposals that involve animal experimentation and to provide oversight of laboratories. The amendments also increase civil and criminal penalties for AWA violations, and establish an animal welfare information center at USDA's National Agricultural Library."

A.3 Food and Drug Administration

"4. Recommended Mitigation Measures
FDA believes that conformance with this guidance document, when combined with the general controls of the Act, will provided reasonable assurance of the safety and effectiveness of the implantable radiofrequency transponder system for patient identification and health information . We recommend that you (the manufacturer) evaluate your device as described below and, where

appropriate, document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).

A. Biocompatibility

We recommend that you ensure the biocompatibility of the patient-contacting parts of your device by following the tests in the:

- International Standard Organization (ISO) standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

B. Information Security Procedures (Design and Validation)

When discussing the issue of medical devices that store, access, and/or transfer information externally, you should address the concept of information security. Information security is the process of preventing the modification, misuse or denial of use, or the unauthorized use of that information. We recommend that your specifications for a compatible database address the following four components of information security: Confidentiality, Integrity, Availability, and Accountability (CIAA).

- Confidentiality means the characteristic of data and information being disclosed only to authorized persons, entities and processes at authorized times and in the authorized manner. (The assurance that no unauthorized users have access to the information.)
- Integrity means the characteristic of data and information being accurate and complete and the preservation of accuracy and completeness. (The assurance that the information is correct (accurate and complete) - that is, it has not been improperly modified.)
- Availability means the characteristic of data, information and information systems being accessible and usable on a timely basis in the required manner. (The assurance that the information will be available when needed.)
- Accountability is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user.

C. Software Validation

We recommend that you validate the software in your device by referring to the following guidance:

- Guidance for FDA Reviewers and Industry Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff

D. Migration Testing of Implanted Transponder

We recommend that you conduct testing of the implanted transponder to demonstrate that the transponder will not migrate after implantation.

E. Performance Testing of Implanted Transponder

We recommend that you conduct testing of the transponder that will demonstrate that under conditions of use the transponder sends an identification (ID) code and that the ID code is correct. The testing should address loss or corruption of the data, latency and through-put, and be coordinated with the electromagnetic compatibility (EMC) performance of the implant, scanner and wireless data link.

F. Performance Testing of Inserter

We recommend that you demonstrate the functionality of the insertion device by conducting testing that demonstrates that inserter can properly implant the transponder.

G. Performance Testing and Hazard Analysis of Electronic Scanner

We recommend that you address the functionality of the electronic scanner by conducting performance testing and hazard analysis that demonstrate the scanner utility in reading the transponder identification code.

H. Electromagnetic Compatibility

We recommend that you demonstrate the basic EMC of the device (i.e., transponder and scanner together) by performing EMC testing in accordance with the following FDA- recognized standard:

- IEC 60601-1-2 (Second Edition, 2001) Medical electrical equipment - Part1: General requirements for safety; Electromagnetic compatibility - Requirements and Tests, or its equivalent.

I. Electrical Safety Performance Testing

We recommend that you demonstrate the electrical safety of your device by following the testing in:

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety

J. Sterility

We recommend that the transponder and inserter be sterile with a sterility assurance level of 10^{-6}. We also recommend that you address the sterility of your device by reviewing the following:

- Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA.

K. Magnetic Resonance Imaging Compatibility

We recommend that you demonstrate the magnetic resonance imaging compatibility of your device by following:

- ASTM F2052-02 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-02a Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213-04 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119-01 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

In addition, you should also address the EMC concerns for implant exposure to the significant magnetic and radiofrequency emissions from MRI, including concerns for implant malfunction or damage from MRI exposure and the use of the scanner during MRI procedures.

L. Labeling

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use.[2]

We recommend that instructions delineate the technological features of the specific device and how the device is to be used on patients. We recommend that the instructions encourage local/institutional training programs designed to familiarize users with the features of the device

and how to use it in a safe and effective manner. If there are any precautions or warnings, which relate to packaging or sterility, these should be repeated on the package labels.

We also recommend that you provide after surgery care instructions to the patient. See also Guidance on Medical Device Patient Labeling.

Final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce."

A.4 IEEE Code of Ethics

"We, the members of the IEEE, in recognition of the importance of our technologies in affecting the quality of life throughout the world, and in accepting a personal obligation to our profession, its members and the communities we serve, do hereby commit ourselves to the highest ethical and professional conduct and agree:

1. to accept responsibility in making decisions consistent with the safety, health, and welfare of the public, and to disclose promptly factors that might endanger the public or the environment;

2. to avoid real or perceived conflicts of interest whenever possible, and to disclose them to affected parties when they do exist;

3. to be honest and realistic in stating claims or estimates based on available data;

4. to reject bribery in all its forms;

5. to improve the understanding of technology; its appropriate application, and potential consequences;

6. to maintain and improve our technical competence and to undertake technological tasks for others only if qualified by training or experience, or after full disclosure of pertinent limitations;

7. to seek, accept, and offer honest criticism of technical work, to acknowledge and correct errors, and to credit properly the contributions of others;

8. to treat fairly all persons and to not engage in acts of discrimination based on race, religion, gender, disability, age, national origin, sexual orientation, gender identity, or gender expression;

9. to avoid injuring others, their property, reputation, or employment by false or malicious action;

10. to assist colleagues and coworkers in their professional development and to support them in following this code of ethics."