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WIRELESS COMMUNICATION AND CONTROL SYSTEM FOR PORTABLE MICRO-ELECTROMECHANICAL DEVICE FOR REAL-TIME BLOOD SAMPLING AND GLUCOSE ANALYSIS (ELECTRONIC MOSQUITO)

Tristan D. Jones, Karan Kaler, Michel Fattouche, Martin P. Mintchev

Abstract: *This study is a continuation of the development of the "Electronic Mosquito," a minimally-invasive blood sampling and analysis device. Wireless communication is a pivotal feature of the Electronic Mosquito in terms of usability and future applicability. The present article describes the design process used to construct a working wireless communication link using an established and reliable protocol. The resulting wireless link performed to specifications, with an empirically determined range of about 20 feet. Power consumption analysis indicated that the wireless system could operate for 100 days off of a CR2032 battery without any power control, and likely longer if power management is implemented in the software. The adopted communication protocol also appears to be a likely candidate for the creation of a Personal Area Medical Network standard which could greatly benefit modern medicine as well as the Electronic Mosquito.*

Keywords: *Electronic Mosquito, Diabetes, Non-Invasive Monitoring, Control Systems, Wireless, ANT*

ACM Keywords: *Medical Information Systems*

List of Abbreviations

ADC	*Analog to Digital Converter*
BG	*Blood Glucose*
GOx	*Glucose Oxidase*
JTAG	*Joint Test Action Group port*
MEMS	*Micro-electromechanical system*
PAMN	*Personal Area Medical Network*
RX	*Receive*
SBGM	*Self Blood Glucose Monitoring*
TX	*Transmit*

1. Introduction

1.1. Diabetes Mellitus

Diabetes Mellitus is an affliction of pandemic proportions, affecting an estimated 171 million people worldwide in the year 2000. Furthermore, that number is expected to rise to 366 million by the year 2030 [1]. Taking into account historical and projected world population dynamics yields an increase in prevalence from 2.8% to 4.4% by the year 2030 [2], clearly making diabetes an important and immediate health concern.

Diabetes is characterized by abnormal blood glucose levels resulting from either insulin deficiency (Type 1 diabetes) or insulin insensitivity (Type 2 diabetes) [3]. Both conditions commonly result in dangerously high blood glucose levels and this seems to be the cause of the various diabetic side effects such as retinopathy leading to blindness, various neuropathies that can lead to limb amputation, nephropathy (kidney damage), and eventually death [4,5].

Type 1 diabetes is often referred to as juvenile diabetes as it commonly arises in infants and is generally thought to be largely a genetic condition with a minor environmental component. In this form of the disease, the β-cells in the pancreas that produce insulin are destroyed via an autoimmune process [6, 7]. Without insulin the human body cannot absorb glucose and as a result it builds up to toxic levels in the blood stream [3]. Type 1 diabetics must monitor their blood glucose levels in order to administer insulin and keep these concentrations at non-toxic levels.

Sufferers of Type 2 diabetes typically develop the disease later in life and as a result it is known colloquially as adult-onset diabetes. While the pancreatic β-cells of sufferers are functioning correctly, the cells in the body develop a resistance to the insulin hormone with the result that glucose once again can accumulate to toxic levels in the blood [7, 8]. While causation has not yet been shown, there is a strong correlation between obesity (especially childhood adiposity) and development of type 2 diabetes later in life [9, 10, 11].

1.2. Current Treatment

Current treatment for diabetes consists of increased exercise and dietary control, as well as self blood glucose monitoring (SBGM) [3, 12]. Current leading-edge treatment/management regimes for diabetes typically consist of two approaches: implanted, continuous glucose monitoring devices [13, 14] and non-invasive monitoring devices typically using reverse iontophoresis [13, 15]. Unfortunately all of these methods suffer from several severe drawbacks which are discussed below.

1.3. "Finger-poking" Self-Monitoring Method

The "finger-poking" method of SBGM is presently the most common technology used by diabetics to monitor their condition. It consists of a spring-loaded needling device and a reusable digital sensor for glucose. The needle is used to create a small wound, typically on the fingertip, from which a small blood sample can be harvested and placed in the glucose meter. The glucose meter then uses a chemical reaction involving Glucose Oxidase (GOx) to generate and display the concentration in units of mmol/L [13]. Two major brands of this type of system are OneTouch (Johnson & Johnson, New Brunswick, NJ, USA) and Accu-Chek (Roche Diagnostics, Laval, QC, Canada).

Unfortunately this technique suffers from the fairly major drawback that it is invasive and painful for patients, which results in significant problems with patient compliance [16]. Furthermore, finger-poking only produces 2-8 glucose measurements a day, which is quite low and limits the information available about the patient's glucose dynamics. It has been shown in several studies that increasing the rate of sampling improves glycemic control and hence slows progression of the disease and its symptoms [17,18].

1.4. Non-Invasive Glucose Sensors

The only non-invasive glucose-sensing technology to have gained market approval in the United States has been the Gluco-Watch (Cygnus Inc, Redwood City, CA, USA). This device uses reverse-iontophoresis, the application of electrical fields to the skin, to draw glucose out of the interstitial fluid to the electrode where its concentration can be measured.

Reverse-iontophoretic glucose sensing methods draw glucose from the interstitial fluid, which lags behind the glucose concentration in the blood by 18-20 minutes [15]. Furthermore, the ions are not drawn to the electrode at the same concentration as they exist in the interstitial fluid. As a result of these two properties, reverse-iontophoretic devices (including the gluco-watch) need to be regularly calibrated against a known blood glucose concentration, normally obtained by the finger-poking, SBGM technique. Therefore, this painful procedure is still present, albeit slightly less frequently [15, 19].

1.5. Implantable Glucose Sensors

The most popular commercially available implantable continuous glucose monitoring device is Medtronic's MiniMed Paradigm (Medtronic, Minneapolis, MN, USA) that uses a 3-day subcutaneously implanted tube connected to an external sensor to monitor BG levels. Although offering the capability of "continuous glucose monitoring," these solutions cannot avoid problems with calibration. Once again the sampled fluid is the interstitial fluid and thus the system suffers from the same time delays and non-linearities as reverse iontophoretic sensors.

2. The Electronic Mosquito

The Electronic Mosquito (e-Mosquito) introduces several novel technologies and concepts to overcome all of the shortcomings noted in the approaches above [20].

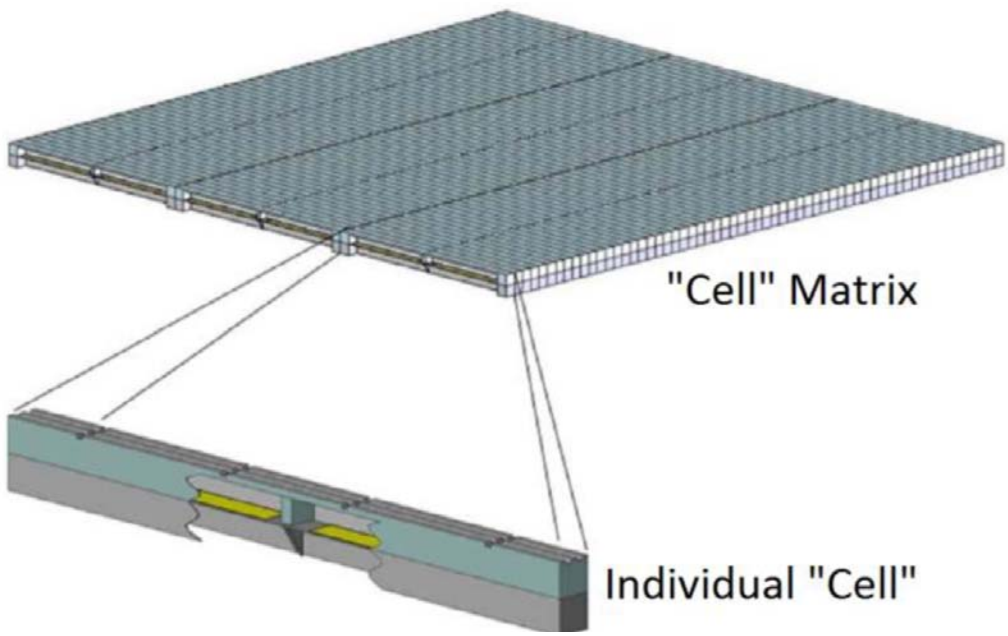

Figure 1. Electronic mosquito "cell" matrix structure showing a closeup of an individual cell as well as the entire matrix of repeated elements [20].

The vision for the device consists of a Band-Aid-like patch (roughly 3" x 3") with a large number (>100) micro-scale "cells" built with MEMS technology (Figure 1). Each "cell" contains of a MEMS microneedle, piezo-electric actuators, and a glucose sensor (Figure 2). Each "cell" is single use only, as the sensor in each "cell" will not be cleaned after use and therefore cannot be reused without contamination of the following sample. The device can then be programmed to use a cell to sample blood glucose levels at an arbitrary interval, for instance every 5 minutes or every 10 minutes. While this is not entirely continuous, the rate of change of glucose levels in the blood are slow enough that sample rates in this range should be essentially lossless. Moreover, with further miniaturization of this technology, the sampling interval can be reduced to well below a minute, if need be.

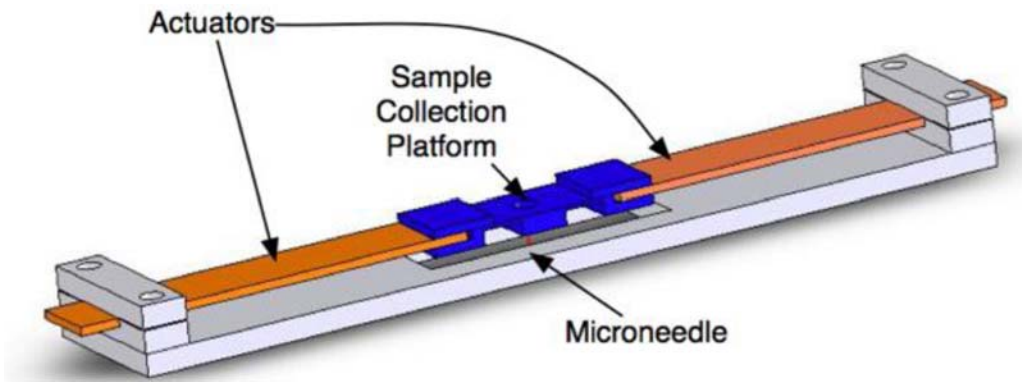

Figure 2. A single "cell" of the e-Mosquito, showing the actuators, microneedle, and sample collection platform where the actual glucose sensor is located [20].

The electrodes in the glucose sensor allow the e-Mosquito to detect the presence of a blood sample. This capability is then coupled to a control system which controls the deflection of the needle actuators. The control system descends the needle by a fixed step amount, and then waits to ensure that no blood is forthcoming. The needle then descends by another step and again waits. This process repeats until blood is detected on the electrodes at which point the needle withdraws (Figure 3). Due to the fact that capillaries lie above nerve endings in many locations in the body (Figure 4), the sampling process should be almost entirely painless.

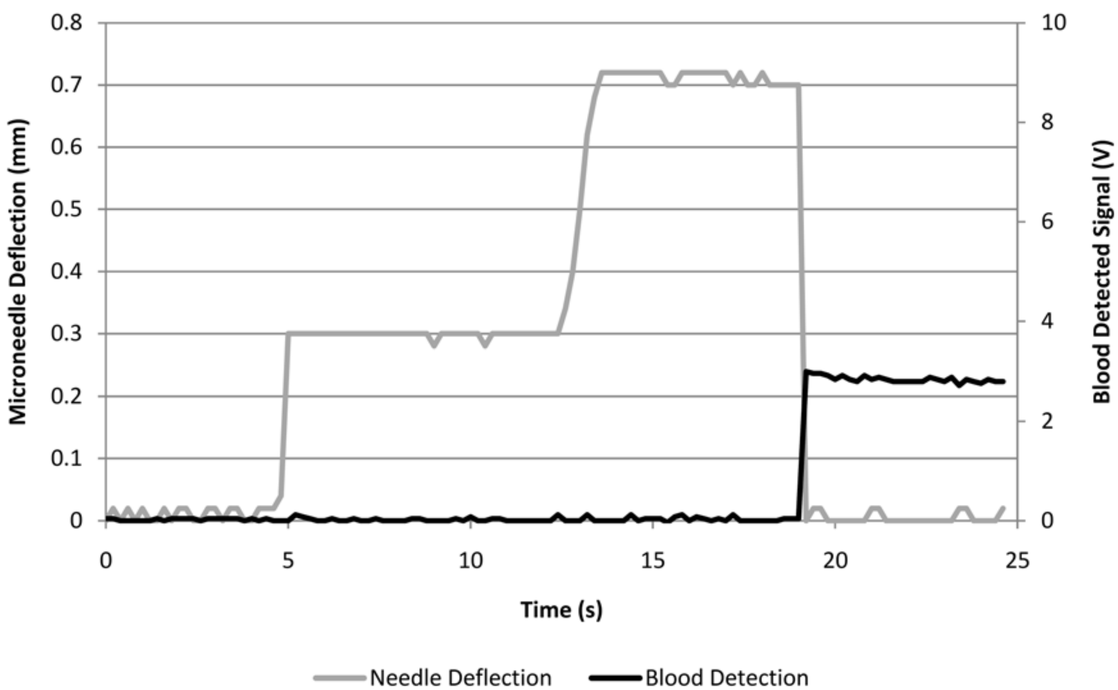

Figure 3. Example of controlled descent of the e-Mosquito needle in an ex-vitro setting. The voltage is proportional to needle deflection downwards. The small step up signal at lower right indicates blood detection on the electrodes [21].

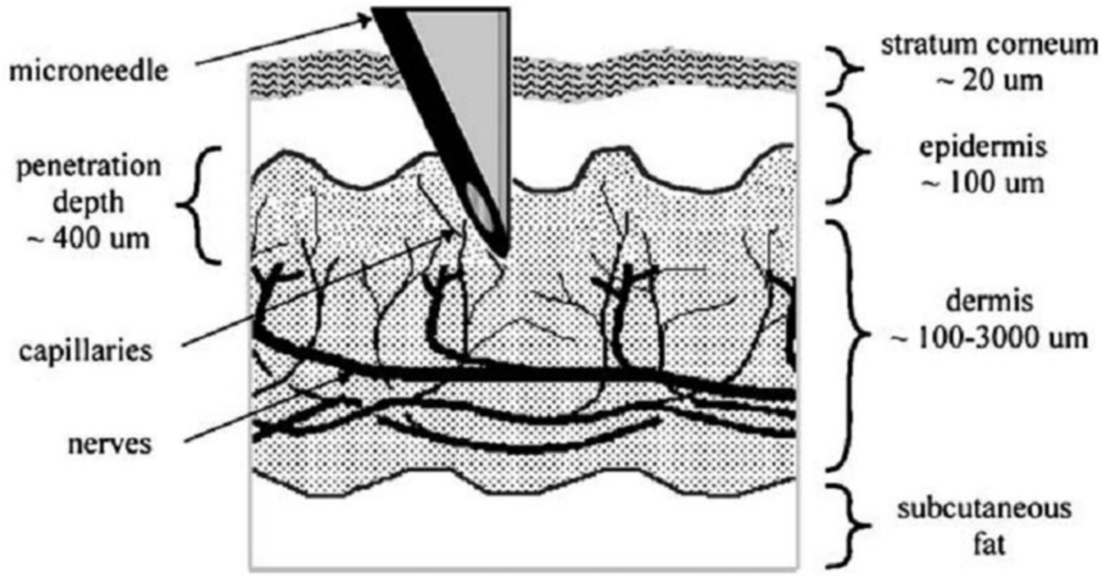

Figure 4. Profile of normal skin at various depths, showing capillary extension above nerve endings. A MEMS microneedle is also shown [21].

The e-Mosquito will permit both high temporal resolution glucose level tracking and in the long-term, a complete artificial pancreas that would allow diabetics to lead normal lives.

2.1. Wireless Communication and Control

In order for the e-Mosquito patch to be convenient for patients to us, it should not require plugging in, and should not have any loose wires to constrict movement or tangle. Furthermore, if the patient were required to be physically tethered to a computer this would severely restrict the patient's freedom of movement.

Wireless data technology enables all of the goals of the e-Mosquito project. Radio-frequency connection to a device such as a health watch can provide near real-time display and recording of data. Connection to an insulin infusion pump will facilitate the creation of a complete artificial pancreas that is almost completely unobtrusive to the patient.

Based on the requirements for the device and the realities of day-to-day living, a bi-directional wireless data link becomes of pivotal importance to the e-Mosquito.

3. Aim of the Study

The primary goal of this study is the development, implementation, and testing of a wireless link for the e-Mosquito. Furthermore, the evaluation of wireless link topographies, security measures, and protocol requirements for the development of a modular personal area medical network (PAMN) is examined and a set of design constraints for a second generation wireless link is proposed in this context.

4. Methods

4.1. Design Methods

The design of the wireless interface was accomplished by using the classical design method. The system constraints were first enumerated and then a design was developed that met or attempted to meet each constraint. The first generation wireless interface outlined here was designed to provide control signals to the e-Mosquito device and to receive data and control responses from the device. At the current stage of the development of the e-Mosquito prototype, the control signals and responses relate primarily to the control of needle penetration and the detection of blood in the sample volume. However, with the addition of a functional glucose sensor, the wireless link is intended to handle glucose data transmission as well.

While the final e-Mosquito would be programmed initially to sample at a specific interval, the current prototype receives its control signals from a connected computer. This computer connects to the e-Mosquito device and receives a configuration message detailing the various analog-digital converter parameters, as well as the current state of every “cell” (blood detected or not and current deflection). The computer is then able to cause sequential “cells” in the e-Mosquito to begin blood sampling by sending a start command (Figure 5).

The list of first generation design constraints is found in Table 1.

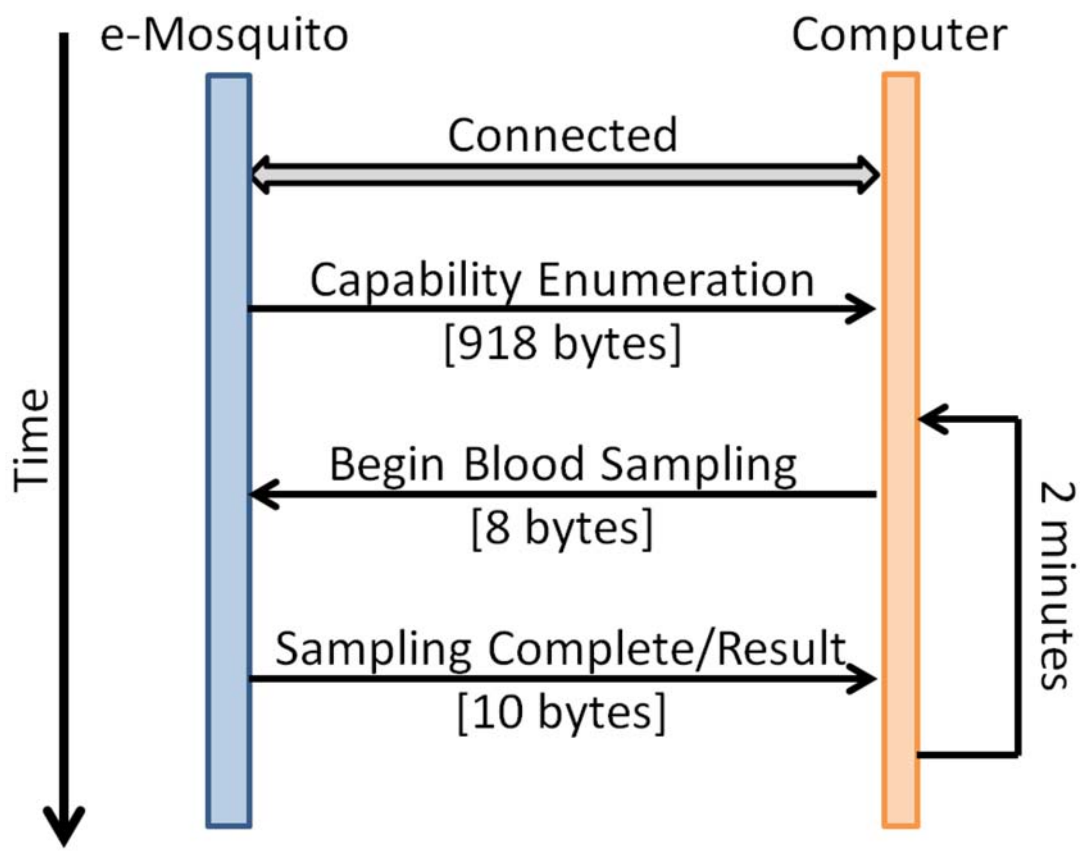

Figure 5. Communication protocol for a computer controlling the e-Mosquito. This case assumes 300 "cells" in the e-Mosquito and a sample interval of 2 minutes.

Table 1. List of design constraints for the first-generation e-Mosquito wireless link.

Constraint	Description
1.1	***Bidirectionality:*** The wireless link must be able to pass both control signals and data in both directions.
1.2	***Low Power:*** The e-Mosquito is designed to use CR-2032 and must operate continuously for a period of 2 days.
1.3	***Transmission Rate:*** The minimum transmission rate required can be calculated from #FIGURE#: $$v_{min} = \frac{(10 \text{ bytes}) + (8 \text{ bytes})}{2 \text{ minutes}} = 0.15 \text{ bps}$$ Of course this rate would cause the initial enumeration to take $0.15 \text{ bytes/s} \times 918 \text{ bytes} = 2.30 \text{ minutes}$ to transmit, which is tolerable, but not desirable. In the interest of maintaining future expandability of the wireless link, it was decided that the bandwidth of the link should far exceed current requirements. A factor of 20,000 times would allow a large number of devices to coexist on the same network simultaneously, as well as provide ample room for expansions to the protocol later. This results in a desired transmission rate of 3kbps.
1.4	***Transmission Fidelity:*** The range of the wireless link should be at least 20 feet so that the e-Mosquito is able to communicate with devices in the same room as the user. Within this range, 99% of packets should be successfully received.
1.5	***PC Connection:*** For the purposes of developing the e-Mosquito, and for end users to archive or transmit their BG data, the wireless link should be able to interface with a standard windows PC.

These design constraints were then used to guide the design process and arrive at a final first-generation link hardware implementation.

4.2. Testing Methods

The prototype wireless communication system underwent testing in a variety of ways. The primary interest was in wireless range and fidelity. In order to quantify this, the wireless-link was tested in two generic hallways as well as outdoors. The number of packets that were successfully received vs. the number of packets that were lost during transmission was taken to be an easy way to quantify signal strength. A laptop was used to collect the transmitted data while the e-Mosquito prototype with an attached wireless chip was used to generate data for transmission. The e-Mosquito prototype was powered by a +5V power supply provided through the JTAG programming interface.

Furthermore, current consumption of the wireless chip was measured by placing an ammeter on the positive supply to the wireless interface. The current consumption was plotted against time over a short period in order to quantify both the idle current draw and the transmitting current-draw. From this an average in-use current was calculated and compared to the capacity of a standard CR2032 battery.

Finally, the wireless link was used to operate the e-Mosquito prototype permanently, constituting an *in situ* test of the system.

5. Results

5.1. Design Results

The design of the wireless system was performed directly from the constraints found in Table 1. The nRF24AP1 wireless chip from Nordic Semiconductor implementing the ANT digital wireless protocol developed by Dynastream (Cochrane, AB, Canada) was chosen based on constraints 1.1 – 1.4, while the high-level architecture was designed based on constraint 1.5.

The nRF24AP1 chip is a transceiver chip, meaning that it incorporates both an RF transmitter circuit (TX) and an RF receiver circuit (RX). This allows it to both receive and transmit messages, fulfilling constrain 1.1 that the wireless link should be bidirectional [21].

The nRF24AP1 has an average current draw of 30 μA [21]. A typical CR2032 button cell battery has a capacity of 220 mAh [19] and assuming ideal characteristics, could provide an average current of $220\ \mathrm{mAh}/48\ \mathrm{h} = 4.58\ \mathrm{mA}$. Thus the wireless link will be consuming on average only 0.655% of the total current available to the e-Mosquito. Conversely, a CR2032 could operate only the wireless link for a period of about 305 days. The current consumption of the nRF24AP1 chip was considered to be small enough that it would not have a significant effect on the performance of the device, satisfying constraint 1.2.

The maximum sustained data rate of the nRF24AP1 is 20 kbps [21], which exceeds the requirement of 3 kbps by a factor of 6.7 times (satisfying constraint 1.3). This also provides significant headroom for future enhancements of the protocol to allow more data to be transmitted.

Unfortunately, the nRF24AP1 documentation does not give any sample range information to allow easy validation of this constraint. However, the sample devices provided with the development kit were tested and demonstrated ranges far in excess of 20 feet with no noticeably missed packets. This allowed constraint 1.4 to be satisfied, with the stipulation that the actual range of the device should be tested and validated later.

The overall architecture was determined by the need for the e-Mosquito to communicate with a computer controller (constrain 1.5). USB was chosen as the interface method on the computer end, as a wide variety of USB interface chips (such as those made by FTDI) and software libraries are available. In order to interface with the wireless chip, a microprocessor (the Texas Instruments MSP430F5438) was used to translate the wireless messages received by the ANT into messages suitable for transmission over the USB port to the computer (Figure 6).

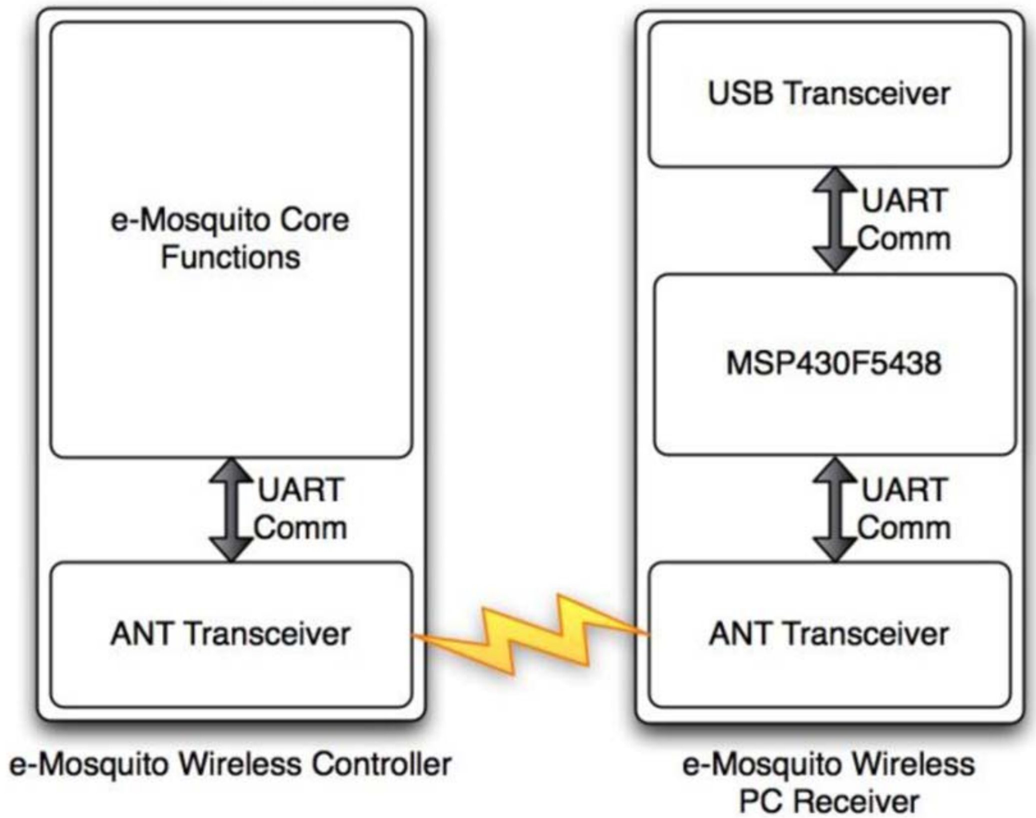

Figure 6. Overall architecture of the first-generation e-Mosquito wireless link. The e-Mosquito transmits data wirelessly to the ANT transceiver, which then translates and delivers the data to a computer via USB [21].

The hardware itself was constructed on a small PCB with discrete surface-mount components for ease of prototyping. The antenna used had an impedance of $50\ \Omega$ and was matched to the nRF24AP1 chip using the design provided in the datasheet (Figure 7) [21].

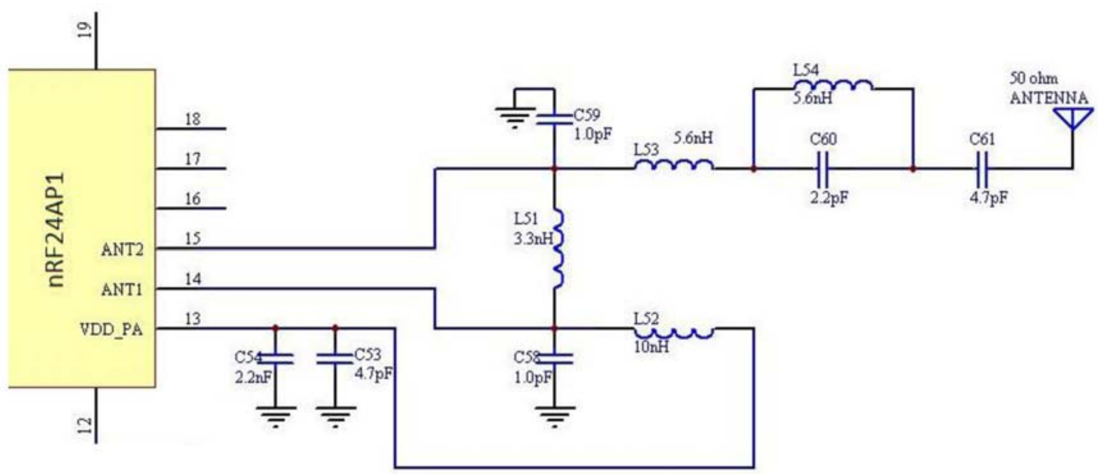

Figure 7. Antenna matching circuitry attached to the nRF24AP1 circuit. Modified from [21].

5.2. Testing Results

The primary concern in testing the wireless link was the range at which it can operate reliably. The wireless communication was tested in three separate environments, all of which had ambient radio noise present. The first two were generic hallways with differing geometry, while the third test took place in a large open outdoor field. The fidelity of the resulting transmission at a variety of distances was approximated as the percentage of packets that were successfully received in an uncorrupted state. The resulting signal fidelity (Figure 8) indicates that the wireless link is 99% reliable to twenty feet in most situations, however hallway #2 had some fidelity issues beginning at roughly 18 feet (70% at 20 feet).

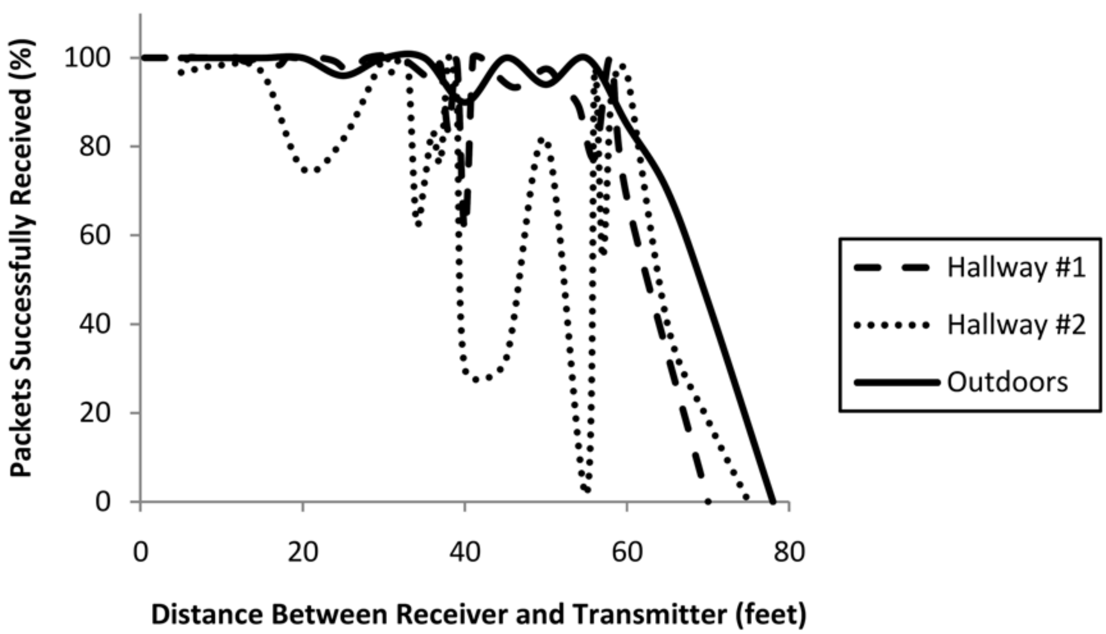

Figure 8. Wireless ANT chip range and signal fidelity in three radio-noisy environments.

Looking at the entire transmission profile out to approximately 80 feet, it becomes apparent that the transmission quality falls rather dramatically at certain points (20 feet, 40 feet, 55 feet) and then recovers. These transmission nodes, coupled with the fact that they are not uniform in location or magnitude across the different settings, indicates that the wireless link is prone to self-destructive multipath interference effects. It was felt during the design stage that the nRF24AP1 chip used would be able to handle this short distance without any issues. However as this is not the case, a packet acknowledge/retransmit system will be implemented (see Section 6 below).

The electrical current consumption of the wireless link is also a primary concern, as this relates directly to the lifetime of the batteries. The e-Mosquito will be disposable and will operate over the course of 1-2 days before replacement, meaning that the demands on the battery are not extreme. Testing has determined that the average current consumption of the wireless link is about $100\ \mu\text{A}$, although the peak current is approximately $15\ \text{mA}$ for $\sim 500\ \mu s$. While the average current draw is about 3 times the $30\ \mu A$ indicated in the datasheet (likely due to additional components such as a power-indicator LED etc.), this still means that the current consumption of the device is still only 2.18% of the total power available to the device (assuming operation over two days. However the peak current does exceed the maximum sustained current draw of the battery and it is unknown presently what effect this will have.

Finally, the wireless link is under continuous use in the laboratory as the primary means of controlling the e-Mosquito prototype. It has been used for a period of 10 months and in that time has shown no noticeable issues. While this is a qualitative measure, it is a strong indicator of the success of the design.

6. Future Directions

The first step to be undertaken to improve the design of the wireless link is to remedy the range issues by implementing a simple acknowledgement response to the protocol. Any message sent by the device will be acknowledged on receipt by a return message being sent. If the original sender does not receive an acknowledgement it will attempt to resend the message at an increasing interval until the message is either received and acknowledged, or times out. This model is quite well known in the communications industry and should easily meet the target of 99% fidelity in a 20 foot range.

The end goal of the e-Mosquito and hence this wireless link is of course an automatic external artificial pancreas (Figure 9). The wireless link allows the e-Mosquito to exist conveniently separate from the insulin infusion pump.

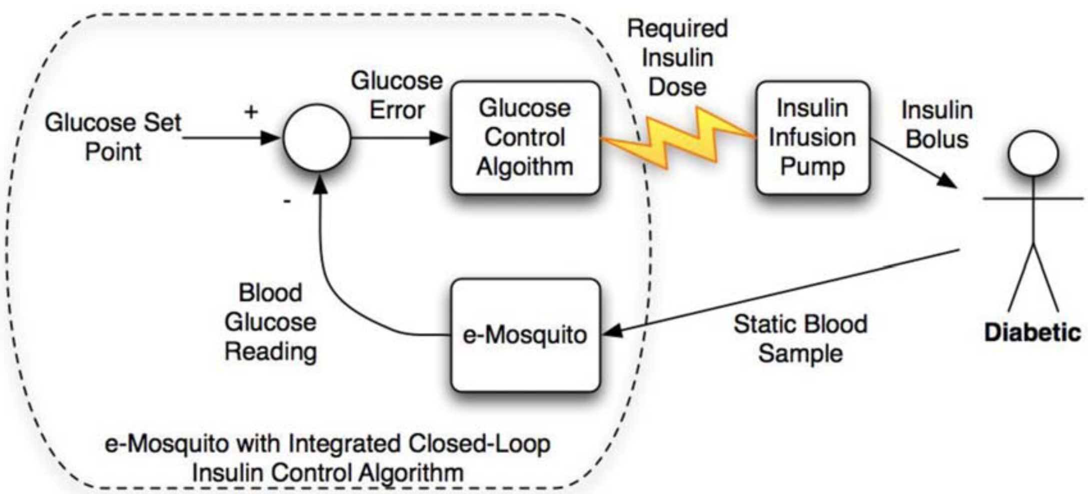

Figure 9. High-level model of the e-Mosquito integrated into a complete artificial pancreas. The required insulin dose is transmitted to the insulin pump wirelessly [21].

Allowing the e-Mosquito to be controlled wirelessly as well as deliver glucose readings also opens up the exciting potential for personal area medical networks (PAMNs) and the second-generation wireless link is being designed to operate in such a manner. The same design process was used as the first-generation link and the constraints table is presented below as Table 2.

Table 2. Design constraints for a second-generation, PAMN-capable wireless link for the electronic mosquito.

Constraint	Description
2.1	***Standard Protocol:*** A standardized communication protocol needs to be developed that can be implemented by a variety of different devices to allow them to interoperate. This protocol design will need to take into account the rest of the constraints.
2.2	***Security Encryption:*** Medical data is subject to strict privacy laws and any devices broadcasting medical data on an uncontrollable medium such as a wireless link. Furthermore, the health and safety of the user could be affected if the device was controlled by an unauthorized signal. RSA encryption using a sufficiently long key that is unique to the patient should be sufficient to maintain the privacy of the network.
2.3	***Dynamic Add and Drop Behaviour:*** Devices coming into range of the network (PAMN) should be able to add themselves to the network if they are keyed to the appropriate patient, and should be able to leave the network if they go out of range. The topology of the network needs to be malleable in order to rearrange from the arrival and departure of devices.
2.4	***Path Redundancy:*** The topology of the network should be redundant, for example organized as a self-healing ring or a mesh network. If a communication channel between two devices is disrupted, the message should be deliverable in another way.
2.5	***Distributed Storage:*** Due to the completely decentralized design of the PAMN necessary by constraints 2.3 and 2.4, there is no centralized repository of data. Instead the devices in the network must store their own data and archives and make this available to other devices in the network. Conversely, the devices must have a manner in determining which device contains the data they are requesting.

7. Discussion

The wireless system designed in this study was sufficient for the continuing development of the e-Mosquito prototype in the lab. However, the multipath echo interference issues need to be addressed. Fortunately, the proposed acknowledge-response method does not require any hardware changes and has been implemented in the software. The transmission rate of the device provides sufficient headroom for many more features to be implemented and many devices to be operated on the same network simultaneously. The power consumption was also minimal and on average should not have any adverse effect on the battery life of the device. However the TX/RX current draw of the link exceeded 13 mA for a very short period, which is greater than the CR2032 maximum sustained current of 3.5 mA. It is not known what effect this might have on the battery life, but no problems have been noted to present, and it is likely the short period of time mitigates any problems.

The more exciting aspect of the proposed wireless link is its future application in an artificial pancreas. An artificial pancreas is the goal of a huge amount of research at present, but the e-Mosquito is ideal for this application since it is painless, hassle-free, and able to sample almost continuously at a high rate. The wireless link is another step in this direction, by untethering the disposable sampling patch from the more permanent implanted insulin pump.

8. Conclusions

The wireless system that was developed for the e-Mosquito prototype uses the nRF24AP1 ANT wireless chip and protocols provided by Nordic and Dynastream (Cochrane, Alberta, Canada). This chip was utilized to develop a first-generation wireless link for the e-Mosquito that fulfilled a variety of design constraints. This wireless system was a basic test-bed for use in the lab and did not implement many of the advanced features that are being implemented in the second-generation setup, including cryptographic security and message acknowledgement. However the device satisfied the majority of constraints placed on the design, and has functioned perfectly in a lab setting for a period of 10 months.

Medical data is slowly migrating to electronic forms in the increased pervasiveness of electronic medical records and electronic imaging and storage. A PAMN is another step along this path with a myriad of potential applications. Patients in range of an open wireless internet linkup could provide data on their health and wellbeing to healthcare providers remotely, and more detailed data will allow in depth and precise personalized diagnosis and treatment. Communication of medical devices permits systems such as paired glucose monitors and insulin pumps, or a heart monitor able to dial a cell phone in case of emergency. The information from multiple devices intercommunicating could be integrated to provide a holistic view of overall patient health, providing a more complete picture of the ongoing disease processes to physicians and caregivers.

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