IMES: An Implantable Myoelectric Sensor


Abstract - We present updated progress on the design, construction and testing of an upper-extremity prosthesis control system based on implantable myoelectric sensors. The miniature injectable implant consists of a single silicon chip packaged with transmit and receive coils. Preparation for human implantation of the IMES system is underway. As part of this process, critical design improvements in the IMES implant were required. Here we report improved functionality of the IMES implant, hardened protection against electrical malfunction and tissue damage.

Keywords - Neuroprosthesis, Myoelectric, Prosthesis, implant, EMG, IMES

I. INTRODUCTION

In order to effectively utilize multiple degrees of freedom a complex mechanical hand prosthesis would offer, a large number of control signals must be collected from the user. Intramuscular EMG signals from multiple residual muscles could be used to provide simultaneous control of multiple degrees of freedom in the prosthesis [1]. Wireless telemetry of EMG signals from sensors implanted in the residual musculature would eliminate the problems associated with percutaneous wires, including infection, breakage and marxualization.

![Diagram of the IMES Prosthesis System](from [1])

A system (Fig. 1) using Implantable Myoelectric Sensors (IMES) would consist of multiple implanted EMG sensors ("IMES") and a one-piece prosthesis. The IMES are powered transcutaneously with a 121kHz magnetic field generated by an integrated high efficiency Class E power oscillator [2]. This powering magnetic field is modulated to send control signals to the addressable IMES. EMG signals generated by the residual muscles at each implant site are amplified and digitized by the IMES. A Telemetry Controller within the Prosthesis controls a time division multiplexing (TDM) sequence to orchestrate RF transmissions from each implant so that data from all IMES may be sequentially collected by a receiver in the prosthesis. The Telemetry Controller demodulates the received signals and passes the collected multi-channel EMG data to a Prosthesis Controller. The Prosthesis Controller will control the prosthesis mechanisms in a programmed manner depending on the origin and nature of the collected EMG control signals.

The architecture of this system has been previously described by the authors in [4], and this paper serves to present additional data and to describe design augmentations to the system.

II. SYSTEM ARCHITECTURE REVIEW

The system uses magnetic coupling to allow power and data transfer to, and data transfer from the tissue-encapsulated IMES. All IMES in the system are identical except for an 8-bit laser-programmed device address and 64 bit serial number. The serial number was added to the design since [4] to enable positive tracking of device history as each device transits the manufacturing path toward human implantation. The architecture is designed to support up to 32 active (sending data) IMES on each of two RF bands of operation, 60kHz (Band 1) and 6.8MHz (Band 2). The 13.5MHz Band 3 capability described in [4] was eliminated to save power and space when experimental results confirmed that a satisfactory data link was achievable on Band 2. Band 1 provides a very robust low-rate data link, while Band 2 can operate at approximately sixty-four times the data rate of Band 1. Our system is capable of data transfer on only one band at a time, but may be dynamically band-switched.

III. SYSTEM AUGMENTATIONS

A. 64-Bit Serial Number/Test

In anticipation of the rigorous documentation required of devices intended for human implantation, each IMES now contains a 64-bit LASER-programmed serial
number. This serial number is permanently programmed at the die level, and used to track the history of each IMES from die test to human implantation. In manufacture, the IMES is automatically tested at four assembly levels:

1). Die level – Unpackaged die are tested using a die probe station, with test signals applied through probes touching bond pads on the die surface.

2). Subassembly - The die is attached to a ceramic substrate and sandwiched between two semi-cylindrical magnetic cores. Two coils are wound over the cores and die, and wire-bonded to the ceramic substrate. A surface-mount filter capacitor is also attached to the substrate. This sub assembly is powered magnetically, and a test signal is applied to either end of the assembly.

3). IMES – The Subassembly is inserted into a ceramic cylinder along with some mechanical components and a chemical getter. An endcap is welded to seal the subassembly within. The IMES is powered magnetically, and the test signal is applied between the metal ends of the assembled device.

4). IMES in sterile packaging. – The completed IMES is attached to a carrier printed-circuit board using silicone rubber ties. This carrier board also holds two light-emitting diodes connected antiparallel across the endcaps of the (two-terminal) IMES device. These LEDs serve two purposes; to protect the IMES device from large and potentially damaging electrostatic discharge events during storage, and to provide a source of a test-signal voltage without removal from the sterile packaging. The IMES and carrier board are sealed in a transparent sterilizable envelope. The LEDs within the bag can be illuminated by a calibrated light source modulated with the desired test signal. The LEDs on the carrier board operate photovoltaically when illuminated and thus apply a test signal to the IMES endcaps. The IMES is powered magnetically during the test, so the IMES may be retested immediately prior to implantation without opening the sterile package.

At each stage of automatic test, the IMES serial number is automatically logged with the test data to eliminate the possibility of attributing the test data to the incorrect IMES device.

B. Tissue Protection

An IMES is magnetically powered from an external source. In the unlikely event of a catastrophic integrated circuit failure as might be induced by static discharges during handling or defibrillator stresses applied after implantation, it is possible that the IMES 5-volt internal power supply could, due to damaged circuitry on the IMES silicon chip, be applied between the two IMES endcap electrodes. Such a condition could lead to D.C. current and tissue damage might result. Even if such an event could be reliably detected, it would require interruption of the powering magnetic field to ameliorate the situation, and such an interruption, needed to deactivate a single damaged IMES device, would disable the entire prosthesis control system.

Referring to Fig 2, in order for a D.C. fault current to flow in an endcap electrode, the P-N well isolation junction of the Isrc PFET must fail simultaneously with the gate oxide of the Amplifier NFET and the Poly1-Poly2 oxide of the AC-Coupling Capacitor. An elaborate protection network has been installed between the AC coupling capacitor and the input endcap electrode to prevent damaging currents from reaching the surrounding tissue.

![Diagram of the IMES Tissue Protection System](image)

Because the EMG signals are comparatively small in amplitude, the clamps do not adversely affect the small-signal operation of the IMES. If the aforementioned three-point failure occurs, the majority of the fault current is diverted into the medium-sized clamp, producing a voltage across that clamp of approximately 800mV. The fault current must flow through a Fusible Poly1 Resistor. An analysis, based upon foundry process parameters, predicts that electromigration of the Poly1 material will cause this resistor to fail open after approximately 30 minutes of fault current. Experimental measurements have not yet been made to confirm this prediction. Until the fuse opens, the Poly1 Resistor in conjunction with the Very Large Clamp limit the voltage between the endcaps to about 500mV, which is less than the potential required to dissociate water.

C. Analog Processing Improvements

The amplifier sections in the IMES were reconfigured to reduce system noise as observed in the earlier prototypes. With a maximum gain setting of 78dB and a sample rate of 3kS/s we have measured the noise-referred to input to be 4 microvolts rms in a 6600Hz bandwidth (see Fig. 3). Other circuit changes were implemented to reduce the DC offsets in the amplifiers, the EMG integrator and the ADC.

The high-pass and low-pass corners of the signal
processing chain can now also be controlled by issuing commands over the magnetic link. This feature is useful in changing the anti-aliasing performance as the sample rate is adjusted. In addition, the time constant of the integrating function used to generate the integrated EMG output has been made adjustable. A summary of the programmable analog parameters is shown in Table 1.

Table 1: Programmable Analog Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplifier Gain</td>
<td>19dB-78dB</td>
<td>64 Logarithmic</td>
</tr>
<tr>
<td>High-Pass Corner</td>
<td>4Hz-70Hz</td>
<td>16 Linear Steps</td>
</tr>
<tr>
<td>Low-Pass Corner</td>
<td>200Hz-6.6kHz</td>
<td>32 Linear Steps</td>
</tr>
<tr>
<td>EMG Integrator Time Constant</td>
<td>2mS-35mS</td>
<td>16 Linear Steps</td>
</tr>
</tbody>
</table>

As in the prior IMES design, the internal 8-bit ADC can be directed to sample the integrated EMG signal, the “raw” EMG signal, or the internal IMES power supply voltage. A data selector was added between the ADC output and the internal logic to allow readback of the IMES address byte, or any of the eight bytes of the 64-bit serial number.

D. Error Correction

It was previously reported in [4] that phase jitter of the IMES PLL in combination with phase jitter of the reference oscillator in the controller was responsible for the wild-point noise observed in a recovered test signal. Extensive circuit changes in the IMES PLL have reduced this phase jitter from approximately 20 degrees rms to under 1 degree rms. A silicon copy of this integrated PLL circuit is used as a reference in the newly designed controller.

In addition to PLL jitter, low SNR conditions or the presence of interference could also contribute to an increased bit error rate. To address this situation, inside the IMES a 4-bit Hanning code is calculated from the 8 data bits. As previously described, the IMES logic may be directed to send 0 to 16 bits per sample. The first 8 bits consists of the data sample, and the next 4 bits consist of the Hanning code. To allow error correction, at least 12 bits per sample must be sent.

The test results reported here were collected with the original prototype controller which has a reference oscillator with 20 degrees rms phase jitter. The reported bit error rate is about 15%. In spite of this large bit error rate, the use of the Hanning code results in good-quality EMG data.

E. Miscellaneous Design Changes

Circuit offsets in the FSK demodulator were responsible for unreliable inward data transfer via the magnetic link. Larger transistors, in combination with higher bias currents and strategic layout were used to lower the offsets to acceptable levels.

In the earlier prototype IMES, the RF telemetry coil was wound directly on top of the 121kHz power coil used to couple power from the 121kHz magnetic field. Interaction between the two coils diverted a considerable amount of RF power back into the 121kHz coil. By winding the coils side-by-side on the same core (see Fig. 3), RF losses in the 121kHz coil were correspondingly reduced thus allowing for a smaller sized RF driver. This factor of five reduction in RF driver size reduced IMES power consumption as well as lowering the voltage ripple on the internal IMES 5V power supply.

F. Experimental Results

A photograph of the IMES device in three states of assembly is shown in Fig 3. At the top is the IMES integrated circuit die. In the center is shown an IMES Subassembly placed in a cutaway ceramic package for illustrative purposes. Note the chip capacitor soldered on the left side of the ceramic substrate. The die bond pads are just visible on either side of the magnetic core. The RF coil is the small coil wound over the core on the left side. The 121kHz coil is the larger coil. A completed IMES assembly is shown above the scale.

To illustrate the operation of the IMES, a single IMES was used to collect surface EMG signals from the right forearm of a human subject. The results are shown in Fig. 4 through Fig. 6. 1cm x 2cm disposable pacing electrodes were used, and spaced approximately 10cm apart along lower arm flexors, about 5 cm below the
elbow. The subject alternately relaxed and clenched his fist to produce the surface EMG signals. The test conditions are described in each figure and accompanying caption.

IV. DISCUSSION & CONCLUSION

Use of EMG signals for control of prosthetic limbs has been historically plagued by unreliability of the surface EMG sensors due to movement artifacts, wire breakage, inconvenience of doffing and donning electrodes, maintenance of skin condition, and repeatability of placement. In addition it is difficult to obtain more than 2-3 degrees of freedom from the extracorporeal surface sites. The IMES systems offer the potential to utilize up to 18 muscles in the residual limb that are normally used for hand control.

The geometry typical of residual limbs with an enveloping prosthesis is ideally suited for the transcutaneously magnetically coupled IMES device. It is unknown whether injection of the IMES through a 12-gauge hypodermic needle or surgical implantation of the IMES will become the preferred method of placement.

As the DARPA-funded revolutionary prosthesis project progresses, the IMES is anticipated to become a critical element in the neuromuscular interface. The advances presented here, for the IMES system, are notable as the IMES advances towards qualification for human implantation. A series of animal and human percutaneous wire experiments are currently underway to evaluate the IMES in actual in vivo operation.

REFERENCES