Stimulating and Sensing Network Inside the Human Body

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Abstract—*The Alfred Mann Foundation is developing a network of up to 850 injectable devices that have stimulating, sensing and communication capabilities.*

Each of the devices is coordinated via radio signals a hundred times a second by an external small module. All the devices are powered by lithium-ion rechargeable batteries. The stimulating, sensing, and communication circuits are designed to be highly power efficient to maximize battery life. The stimulator can be programmed to deliver pulses in the range: 5 µA to 20 mA, 7 µs to 2000 µs, and frequencies up to 4000 Hz. Bursting, ramping, and other stimulation features are included. The voltage sensor covers the range 10 µV to 1.0 V with bandpass filtering and data analysis. The implant also contains sensors for pressure, temperature, DC magnetic field, and distances between implants

I. Introduction

Functional Electrical Stimulation (FES) has been elusive for restoring significant function to limbs and other organs, specifically for those with stroke and spinal cord injuries.

Five apparent reasons for this situation are:

1) *Extensive surgery* involving pockets, tunneling, long wires and skill from the surgeon. For example, the 8+ channel Free Hand System [1] and the 20+ channels Nucleus FES22 [2] required more than 4 hours and 15 hours of surgery respectively to implant.

2) *Excessive continuous surface areas of the implant and wires:* All implantable devices may present a risk for microorganisms to form a biofilm and ultimately conquer the whole surface of the implant system.

3) *RF powered devices:* Two problems are encountered with these devices: a) maintaining proper orientation of power transmitting antenna with respect to the implant and b) the discomfort of wearing an antenna and battery powered transmitter, especially for long-term use.

4) *Lack of coordinated sensors:* Most systems require one or more sensors in different parts of the body to coordinate functions. Many sensors are external and require wires going around the body. In the market there are not many implantable sensors. Sensors and stimulators from different manufacturers have to be connected, and the interface becomes a serious engineering project, usually involving wires strung around the body, and often improperly matched electronically.

5) *Lack of flexibility and expandability:* Extensive advanced planning is required for each system. The exact number of sensing and stimulating channels might not be known until the first few have been implanted and tested.

II. Present Status

The functional electrical stimulation battery powered injectable microstimulator/sensor (FES-MSS) concept has become a reality through the continued development of submicron complementary metal oxide semiconductor (CMOS) processes that provide both high speed for communications and low power for long-life battery-powered systems. The FES-MSS overall system block diagram is shown in Fig. 1.

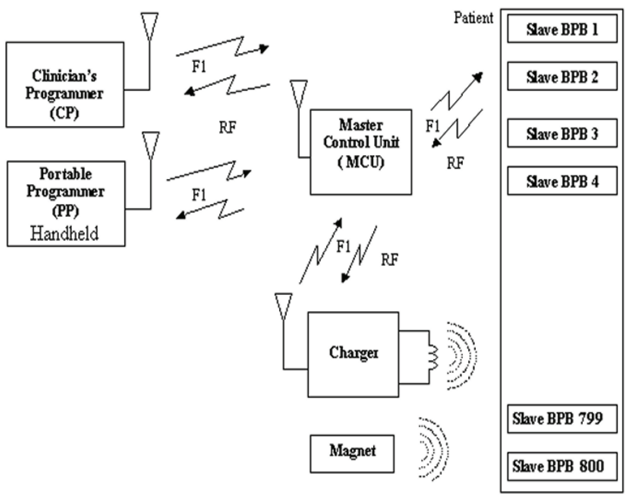

Fig 1. Overall system block diagram.

Communications between the FES-MSS devices and a single, centralized Master Control Unit (MCU) defines the system connectivity. The MCU may be external and is considerably larger and less resource-limited than the micro implants In the final design it is expected to have a size similar to a PDA. Presently it is the size of a small cigar box.. The "star" architecture, commonly used in standard mobile wireless technologies. In order to enable bi-directional access for all implants, a framed "Time Division Multiple Access" regime with time division duplexing between Downlink and Uplink is used.

Because the system is time division based, each implant can maintain a low duty cycle to reduce power consumption. For a typical low-power UHF receiver that draws 5 mA from a 1.8 V supply, a duty cycle of 0.1% is required to maintain average power consumption below 10 µW. The main requirement from the FES-MSS system is to achieve this low average power while maintaining regular communications between up to 800 implants and the MCU.

It is well known from communication theory that using coded waveforms along with coherent demodulation leads to the highest power efficiency [3]. The implant uses a crystal controlled local oscillator, combined with a digital delay locked loop (DDLL) to maintain continuous timing accuracy relative to the MCU. The modulation and coding for the micro-device communication system was selected by compromising between decoder complexity and performance. This compromise results in a quad-phase modulation combined with a forward error correction scheme

Fig. 2 shows the chip functional block diagram explaining the functional planning and division between analog, digital, and firmware blocks.

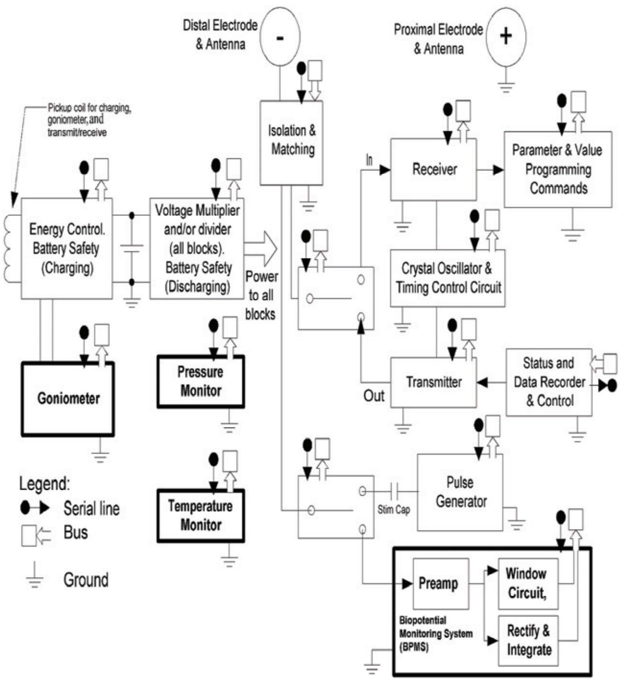

Fig 2. FES-MSS simplified internal block diagram

The FES-MSS is a 3 mm cylinder that is 25 mm long; ceramic covers the electronics and titanium covers the battery, Fig.3.

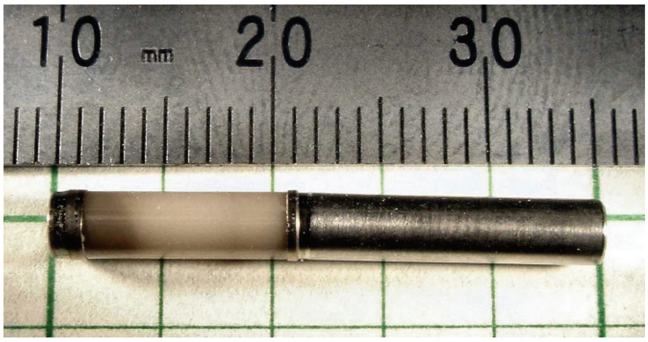

Fig 3. Photograph of typical FES-MSS implant.

A surgical kit has been qualified for introducing microstimulators. This introducing method is considered to be minimally invasive. Probes of a size of 0.5 mm identify the target stimulation or sensing site. These probes guide a dilator to the site for placing the implant. The implant is then activated at the target area to insure therapy and/or biological signal integrity through real-time feedback. A dissolvable suture attached to an eyelet at the end of the implant allows retrieval and repositioning up to seven days post implantation. A typical surgical kit is shown in Fig. 4.

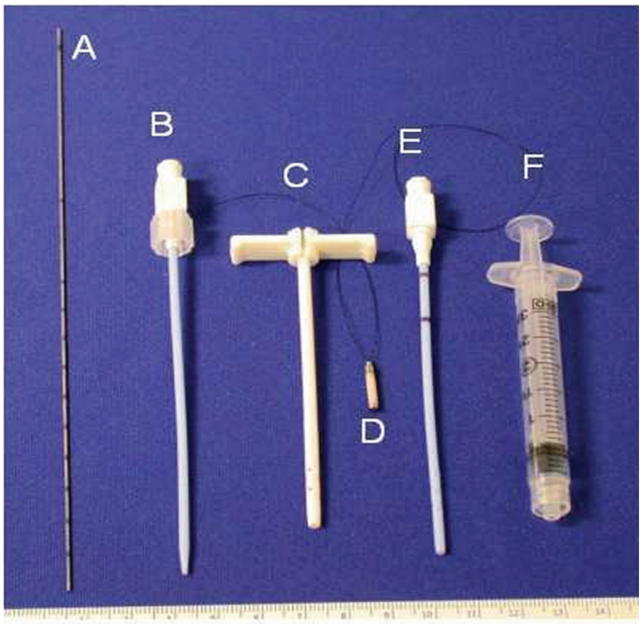

Fig. 4 Surgical tools used to inject the FES-MSS implant. A: Probe electrode, B: Dilator, C: sheath, with holes, D: RF microstimulator with suture, E. Ejection Tool (2 marks), F: 3 ml syringe, with normal saline.

Implants in sheep and rats developed normal encapsulated coatings that prevent migration [4]. The thresholds were mainly below 2 mA and 200 µA. The capsule in rats consisted of compact laminated layers of fibro-collagenous tissue varying from 50 to 100 µm in thickness. Their histological characteristics were the same as pacers and other implantable biocompatible devices. Stimulation thresholds stabilized in sheep and rats in about six weeks.

The battery system in the rechargeable FES-MSS is a novel long-term stable Lithium Ion chemistry developed specifically for implantable devices. The research team at Quallion LLC fabricated the smallest cylindrical rechargeable battery ever built (2.7 mm in diameter and 13 mm long) (Fig. 5). Because the battery must be implanted in the human body, the team developed a proprietary Zero-Volt™ technology, which allows the battery to be kept in a deep-discharge state for long periods of time without negatively affecting battery life.

Fig. 5 Rechargeable Li Ion battery for implant devices

The sensing system is based on utilizing the same filtering and windowing traditionally employed for neurophysiologic research. The amplifier has high impedance, low power consumption and low noise. In addition, gain and bandwidth programmability are available to allow for maximum user flexibility. The programming using wirelessly RF telemetry also embedded within the implantable device. The block diagram of the BSAF architecture is shown in Fig. 6.

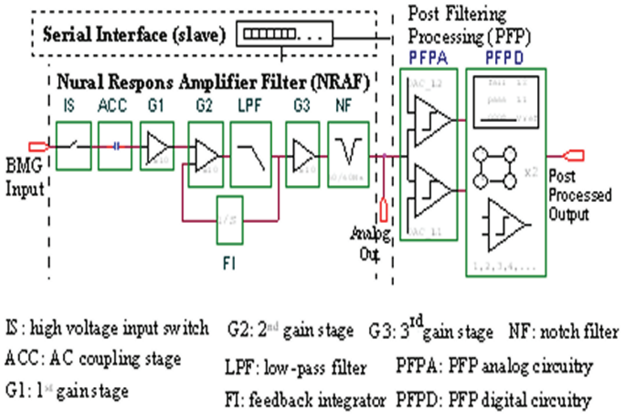

Fig. 6: Block Diagram of Amplifier

One of the stimulating electrodes of the implanted device is used as the floating ground. The same electrode is also used in signal detection, thereby emulating a pseudo-differential input electrode for the amplifier. The implementation of the internal amplifier is achieved using a differential topology with a controlled common-mode bias voltage so that optimum common mode rejection is achieved. This circuit allows reliable EMG/ENG detection. The programmable nature of the amplifier as well as internal shunting circuits allow for a fast recovery.

Angle and distance measurements (goniometry) require t close coordination of transmission and reception of magnetic fields facilitated by the communications system. The distance measurement system is based on generating a low frequency (127 kHz) magnetic field from one of the implanted devices and measuring the strength of this field at another location by another implanted device (Fig. 7).

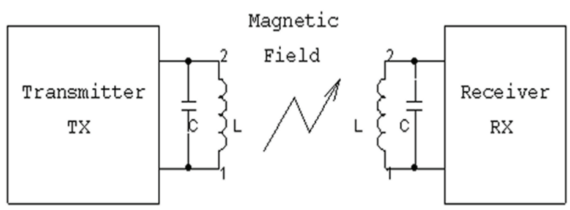

Fig. 7 Goniometry System Principle.

The reasons for this choice are the following:

1) Unlike RF fields, the low frequency magnetic field has very little interaction with the body.

2) The strength of the field drops with the distance very rapidly, approximately following an inverse cube law. This has the advantage of reducing the effects of reflections, interactions with far objects, with other patients having similar goniometry systems or with other sources of interference.

3) The magnetic field generator or sensor (which are tuned coils) can be also used to receive power from an external, larger coil to charge the battery of the implanted

device. The goniometry system will not be able to work during battery charging but that will happen only for a small fraction of time (about 20 minutes a day).

The coils for the goniometry transmitter and receiver are identical and tuned to 127 kHz, any of them can function either as goniometry transmitter or receiver. For optimal efficiency each coil (540 µH) has a cylindrical ferrite core and a Q of 21.

The relative orientations of the transmitter and receiver (TX/RX) coils are important. The best results are obtained when the coils remain either parallel or co-axial during movement, otherwise the signal strength is not monotonic with distance, and more complex computations are required. Results show that small misalignments are not critical. For a 45^0 misalignment the signal strength drops by cos (45^0)=0.71 and the distance error is $(0.71)^{1/3}$=0.89 (11% error).

For monitoring multiple movements, like the fingers of one hand, one fixed transmitter can work with multiple receivers. If two different systems must co-exist, such as one for each hand, they must not interfere with each other. Our solution is to use slightly different frequencies digitally filtered in adjacent 90 Hz bands.

III. PROSTHETIC MICROSENSOR/MICROSTIMULATOR INTERFACE

These microsensors can be used to detect the EMG from the muscle segments in the stump and then relay this information to control joint motor actuator in the prosthetic limb. Also, sensor (temperature, touch, joint angle, and pressure) can be relayed by radio to microstimulators under the skin of the stump to indicate different sensors being activated. See Figure 8.

IV. PROSTHETIC PERIPHERAL NERVE INTERFACE

A 128 channel wireless battery powered stimulating/sensing electrode system using the same communication stimulating and sensing specifications as 128 injectable micro devices is described here for use as an interface between a peripheral nerve and an artificial limb. The stimulation or sensing can be unipolar or bipolar between any pair of electrodes. A slanted bed of nails (SBON), similar to that described by Branner, Stein, and Normann (2001)[5]or any other electrode array can be used.

This electrode array contains a hermetically sealed stimulator/sensing IC chip and multiplexing command system. It is mounted on a peripheral nerve with the electrodes making contact with the neurons as described y Dhillon, Lawrence, Hutchinson, and Horch (2004)[6]. This array is connected by a thin flexible cable to a battery powered 128 channel high speed communications transceiver (BPX). The BPX is a rounded disk about one inch in diameter and 6mm thick. The BPX communicates via high speed radio signals with a master control unit (MCU) in the artificial limb. Ever 11 ms there are 128 bidirectional radio signals between the BPX and the MCU. The MCU is connected to surface, temperature, and joint angle sensors and motor control actuators in the artificial limb. The system is capable of handling a combination of 128 sensors and stimulation channels. The advantage of this system over magnetically powered sensing/stimulator systems is that this system only uses the small and light weight batteries in the MCU for coordination computation and communication only. All the batteries in this system are rechargeable lithium ion. See Figure 9.

V. HUMAN EXPERIMENTS

Coordinated stimulation between 5 and 8 injected stimulators have been tested in 7 human stroke patients, with partially paralyzed arms [7]. These were performed with RF powered injectable stimulators to develop experience. Injections, in many cases, could be performed in about 15 minutes, but in others took over an hour to find the optimum position. We are now working to improve the positioning.

VI. FUTURE PLANS

The application specific integrated circuits (ASICs) for the FES-MSS along with a small number of discreet components are being integrated into a final package for preliminary in vitro testing by 2007. External systems such as the clinician's programmer, portable programmer, MCU, charger and other non-surgical accessories, etc., are being developed currently.

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REFERENCES

[1] P.H. Peckham, M.W. Keith, A.A Freehafer, "Restoration of functional control by electrical stimulation in the upper extremity of the quadriplegic patient" J. Bone Surg AM 1988 70: 144-148.

[2] "Nucleus FES22" M. Akay, *Time Frequency and Wavelets in Biomedical Signal Processing* (Book style). Piscataway, NJ: IEEE Press, 1998, pp. 123–135.

[3] "Communications theory" G. B. Gentili, V. Tesi, M. Linari, and M. Marsili, "A versatile microwave plethysmograph for the monitoring of physiological parameters (Periodical style)," *IEEE Trans. Biomed. Eng.*, vol. 49, no. 10, pp. 1204–1210, Oct. 2002.

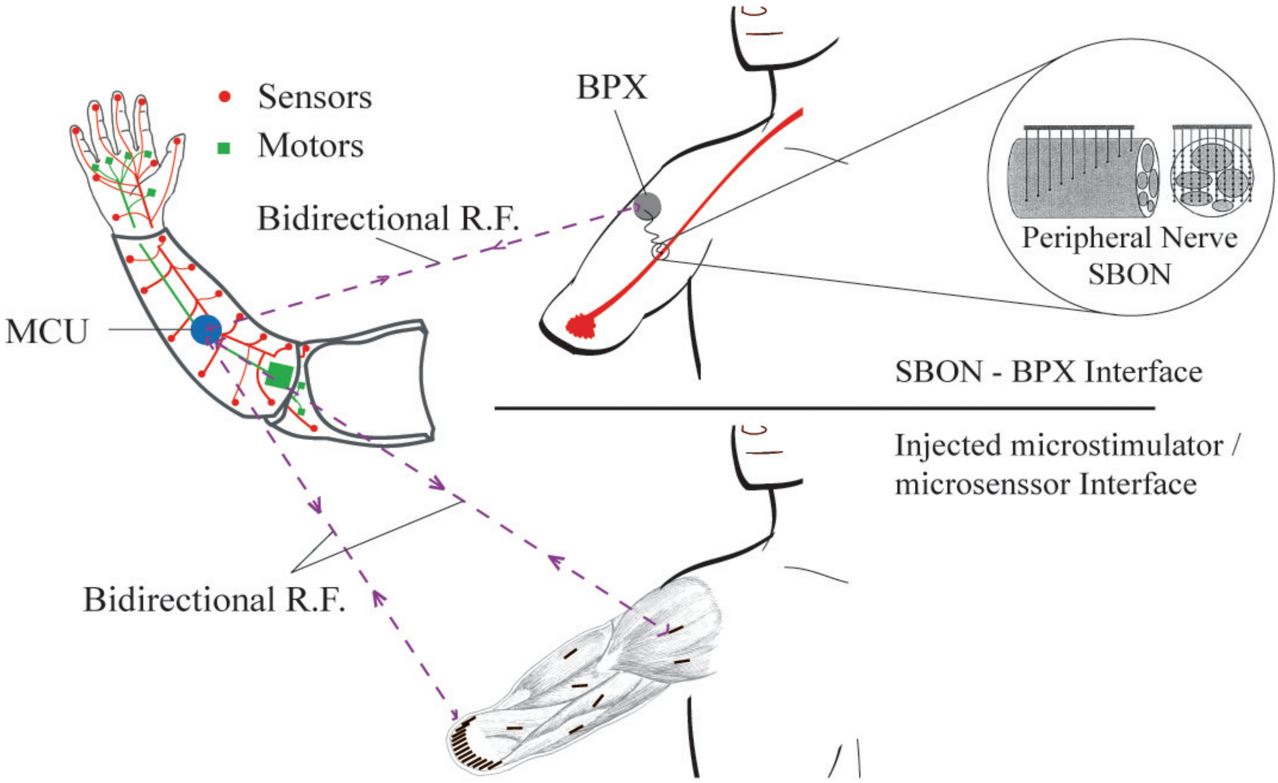

Fig. 8 Control signals between prosthetics and stump for peripheral nerve interface and for microsensor/microstimulator interface.

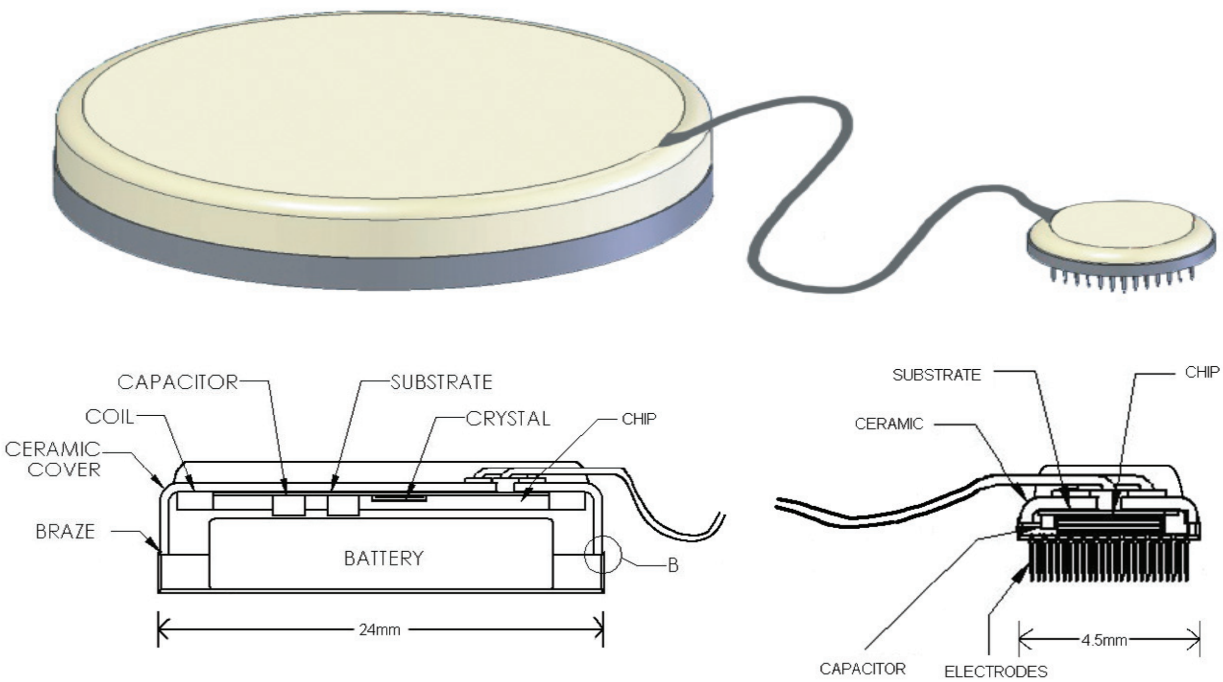

Fig. 9 Details of multielectrode peripheral nerve interface device.

[4] I. Arcos, R. Davis, K. Fey, D. Mishler, D. Sanderson, C. Tanacs, M.J. Vogel, R. Wolf, Y. Zilberman, J. H. Schulman. "Second Generation Microstimulator" Proc 6th IFESS Meeting, Cleveland, OH, June 2001.
[5] A. Branner , R. Stein , R. Normann. Selective Stimulation of Cat Sciatic Nerve Using an Array of Varying Length Microelectrodes. The American Physiological Society, 2001
[6] G. Dhillon, S. Lawrence, D. Hutchison, K. Horch. Residual Function in Peripheral Nerve Stumps of Amputees: Implications of Neural Control of Artificial Limbs. The Journal of Hand Surgery, Vol. 29A No.4:605-615, 2004
[7] G. Cosendai, J.H. Burridge, R. Turk, O. Sparrow, R. Davis, J. Schulman, Post-stroke Upper Extremity Rehabilitation using 5-7 Implanted Microstimulators: Safety and Control Systems, 11th Annual IFESS Conference, Zao, Japan, September , 2006.

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He worked for 11 years at UCLA, with 2 ½ years under Dr. Bernard C. Abbott, in studies on muscle physiology, and later with Dr. Theodore Bullock, previously at UCSD, Department of Neurosciences, investigating problems in neurophysiology. Prior to these positions, he was associated for two years with Dr. Joseph Kaplan of the UCLA Geophysics Department. During the past 30 years, he worked on medical devices for the Alfred E. Mann group of companies. He was the technical founder of Pacesetter Systems, Medical Research Group, Advanced Bionics, Second Sight, Quallion and the Alfred E. Mann Foundation.

Dr. Schulman is a member of IEEE, IFESS, INS, NANS, NCM, AIP, AAAS, AAMI, and ARRL. From 1969 to the present, Dr. Schulman has 82 patents issued and 36 additional patents and 6 provisionals are presently pending at patent office approval.

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Publications:

Injectable Microstimulator for Functional Electrical Stimulation, Med. Biol. Eng. Comput. 29:NS13-NS19 (with G.E. Loeb, C.J. Zamin, P.R. Troyk), 1991

The Transfer of Technology From the Laboratory to the Real World. In Neural Prostheses, R.B. Stein, P.H. Peckham and D..Popovic, eds., pp. 329-341, Oxford University Press, New York (with G.E. Loeb), 1992.

An Implantable Bionic Network of Injectable Neural Prosthetic Devices: The Future Platform for Functional Electrical Stimulation and Sensing to Restore Movement and Sensation. In Biomedical engineering Fundamentals, Joseph D. Bronzino, Trinity College, West

Hartford, Connecticut, USA Series: The Biomedical Engineering Handbook, Third Edition, Chapter 34 pp. 34.1-34.16, (with P. Mobley, J. Wolfe, R. Davis and I. Arcos) 2006.