

One-time Implantable SCS System

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Abstract—A prototype of a one-time implantable spinal cord stimulation (SCS) system using wireless power and data transmission techniques is presented in this paper. The proposed novel ASK demodulator attains high demodulation performance and small area consumption without using any resistor and capacitor. The proposed SCS system utilizes many power saving schemes to reduce the power dissipation, e.g., dual supply voltages on chip, high voltage impulse generation using a small current, etc. The system on chip (SOC) is physically implemented on silicon and integrated in the implant as the system controller. Compared with existing commercial products, the proposed SCS system attains better flexibility and longer operation time.

Keywords—spinal cord stimulation, SCS, wireless power induction, duplex ASK-LSK transmission.

I. INTRODUCTION

A spinal cord stimulation (SCS) method then was well developed basing on the gate control theory [1] to treat the chronically neuropathic pain [2]. Lately, SCS devices are widely implanted in the patients, which are over 14,000 implementation times worldwide annually [3]. Notably, experiments show that the reduction of the pain by SCS is around 70%. The life quality of the patients is then improved by using the SCS technique. The major SCS systems were designed as fully implantable devices. Therefore, the reduction of the discomfortness caused by the replacement surgery and life time extension of the battery become the key research problems of commercial SCS systems [4]. The rechargeable battery of the commercial implantable devices is charged by an outward portable wireless charger. Unfortunately, the portable wireless charger is an independent device, which is inconvenient for patients. Besides, currently commercial SCS products are quite expensive for ordinary patients, which is around 20,000 USD.

Considering the above factors, this study presents a wireless bidirectional transmission scheme with the power and wireless telemetry capabilities. The proposed SCS prototype in this work adopts VLSI (very large scale integer) technology to realize an SCS SOC (system on chip) controller in the pulse generator (PG). The power consumption can be reduced by low power CMOS circuit design to extend the life time of

battery. A Li-ion battery is included in the implant to store RF-induced power, where the power is delivered by coil coupling.

II. ONE-TIME IMPLANTABLE SCS

Fig. 1 shows the structure of the proposed SCS system. Human skin is located between the outward device (External Module) and the inward device (Internal Module). The bidirectional wireless communication in our system employs an amplitude-shift keying (ASK) and a load-shift keying (LSK) techniques. By the inductive link composed of a pair of coils, the power and the digital packets can be transmitted from External module to Internal module simultaneously. In following subsections, each block in our SCS system is described in detail.

A. External Module

External Module generates carrier waves to transmit the digital packet to Internal Module via the inductive link. External Module is composed of an 8051 micro-computer (μC), a Power Transmitter, an LSK (load-shift keying) Demodulator, and an External Coil. The 8051 μC generates serial digital packets to Power Transmitter according to the configuration settings given by users. Power Transmitter modulates the serial digital packets into carrier waves, which are then transmitted by External Coil to Internal Coil. LSK demodulator can restore the same as LSK signal sent by Baseband Circuit of Internal Module.

Power Transmitter and LSK Demodulator: Power Transmitter is utilized to achieve power transmission based on an ASK (amplitude-shift keying) modulation technique [5]. This study proposes a Power Transmitter with a differential output to attain high efficiency power transmission as shown in Fig. 2, which is composed of a pair of Class-E amplifiers. The digital packet signal, packet.in, from the 8051 μC is used to change the amplitude of the output carrier wave on External Coil. Two Darlington pairs, Da1 and Da2, on the two paths are used to provide high current gain, respectively. In path1, the current variation at node A depends on the state of MN1, which causes the emitter current of Q2 to be changed intensely. When MN2 is switched on, the choke, L1, will inhibit impulses at the node B, which is caused by the current variation through L1. To reduce power loss, the switching frequency must be operated at resonant frequency. By given a 2 MHz clock signal, clk, to the

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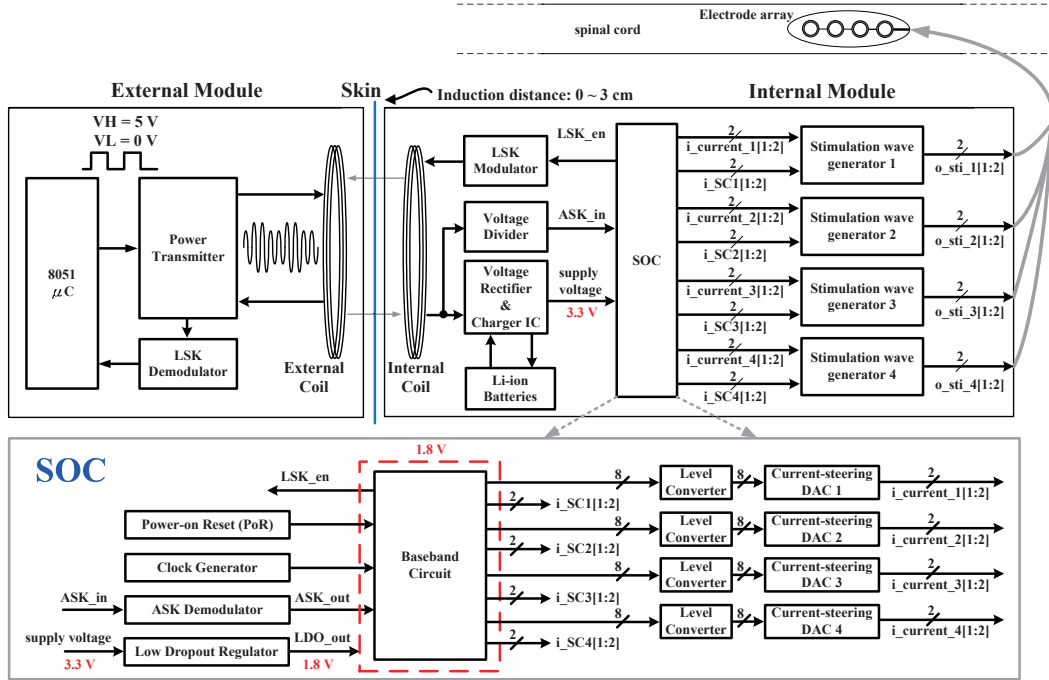


Fig. 1. Block diagram of the proposed SCS system prototype

gate of MN2, node B will generate a carrier wave at the same frequency. On the other hand, the voltage of node C is equal to that of the node B with 180° phase shift due to $\overline{\text{clk}}$, where $\overline{\text{clk}}$ is an out-of-phase signal of clk . By subtracting node C from node B, we can derive a two-time carrier wave amplitude to enhance the output power on External Coil. Therefore, the carrier wave is generated by mixing the choke inhibited impulses and packet_in .

The LSK modulation is based on an impedance reflection technique [7], which is used to transmit digital signals without additional coil. The load impedance variation of the internal LSK Modulator is reflected to External Coil by the inductive link to cause the resonant frequency shift and amplitude change thereof. In Fig. 2, OPA1 and OPA2 are, respectively, unit-gain buffers to duplicate External Coil's signals. Then, the amplitude variation between outputs of OPA1 and OPA2 is attained and then amplified by a difference amplifier composed of R5~R8 and OPA3. A low pass filter composed of R9 and C3 is used to generate a DC potential of the difference amplifier's output signal. Therefore, LSK_en driven by Baseband Circuit in Internal Module can be recovered at the output of OPA4, i.e., LSK signal, by comparison of the DC potential and $V_{\text{ref_1}}$, where $V_{\text{ref_1}}$ is a pre-defined reference voltage.

B. Internal Module

Internal Module is composed of the SOC (system on chip), the Li-ion battery, Stimulation wave generators, and off-chip discretres. According to received configuration setting packets from External Module, Internal Module (or called pulse generator, PG) generates corresponding stimulating waveforms to

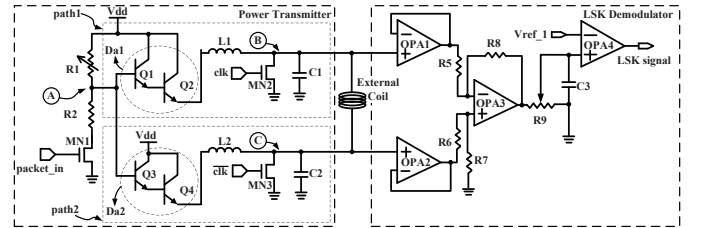


Fig. 2. Schematic of Power Transmitter and LSK Demodulator

the nerves. The detailed description of each block is described as follows.

ASK Demodulator: Fig. 3 shows the proposed novel all-MOS ASK Demodulator to demodulate the modulation waves received by Internal Coil into digital signals. The received modulation wave is rectified to a DC signal by Half-wave Rectifier composed of an MOS diode (Mdiode) and an MOS capacitor (Mcap) in Fig. 3. The headroom of the DC signal is then amplified by the following Envelope detector. When dioout is logic high, V_P is larger than V_N . V_{env} is then pulled high. Contrarily, V_{env} is pulled low when $V_P < V_N$. The Buffer is used to boost the fan-out capability. Therefore, the received wave is demodulated to be ASK_out, which will be restored identical to the original digital packets sent from External Module.

Baseband Circuit: As soon as the received digital packet is demodulated, Baseband Circuit generates corresponding stimulating control signals to the off-chip Stimulation wave

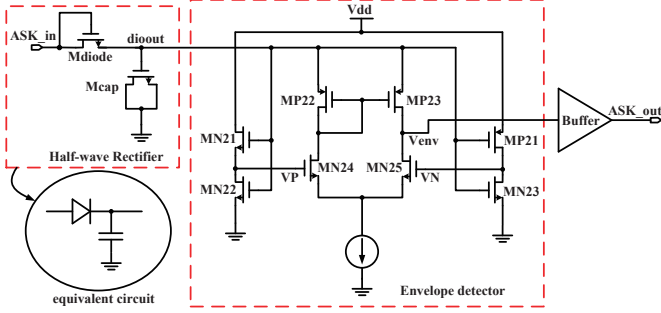


Fig. 3. Schematic of the ASK Demodulator

generator 1~4, as shown in Fig. 1. To reduce the power dissipation, Baseband Circuit employs 1.8 V supply voltage. The proposed Baseband Circuit include a CRC (Cyclical Redundancy Check) error-detecting algorithm [8] to ensure the security of the packet transmission. However, Level Converters are utilized to translate the stimulating control signals into a 3-V voltage level, which drive four Current-steering DACs, individually. Moreover, the features of the stimulation waves are determined by Baseband Circuit, including amplitude, stimulation rate, pulse width, etc.. Notably, Low Dropout Regulator is needed to support Baseband Circuit a 1.8 V supply voltage to reduce power dissipation.

Current-steering DAC (Digital-to-analog converter): Four 8-bit DACs based on the typical current-steering structure, Current-steering DAC 1-4, are used to generate reference currents to Stimulation wave generators, respectively. Stimulation wave generators, respectively, will provide an appropriate amplitude for stimulating waveforms proportional to their own individual currents.

LSK Modulator: We have reported an LSK modulation technique for biomedical wireless communication [7]. After Baseband Circuit completes a CRC verification process, LSK Modulator in Fig. 1 is enabled such that the modulation wave's amplitude of Internal Coil is changed. LSK Demodulator in External Module can demodulate the modulation wave into a digital waveform by the variation of the amplitude, which then will notify the 8051 μ C the status of Internal Module. Thus, the bidirectional wireless communication is built by the duplex ASK-LSK technique.

Stimulation wave generator: The proposed SCS prototype has a 4-channel stimulation array composed of identical Stimulation wave generators 1-4. The schematic of Stimulation wave generator 1 is shown in Fig. 4, which is composed of two independent pulse generators to generate a pair of differential positive and negative stimulation waves. Notably, the spinal cord is stimulated by positive stimulation wave, and the negative stimulation will neutralize the unwanted spurious charge in the spinal cord. The parallel RC circuit composed of R31 and C31 is used to provide an appropriate current for the

base of the bipolar transistor, Q31. When the control signal, i_{SC11} , driven by Baseband Circuit is pulled low instantly, a high voltage impulse is generated at the collector of the bipolar transistor, Q31. The high voltage impulse signal, then, is passed to the output, o_{sti_11} , through the diode, D31, and a capacitor, C33. Similarly, o_{sti_12} generates another high voltage impulse driving by i_{SC12} from Baseband Circuit. Thus, the stimulation wave is generated by the differential signal between o_{sti_11} and o_{sti_12} . Notably, the amplitude of the stimulation wave depends on the input currents, i_{SC11} and i_{SC12} , from Current-steering DAC 1. By tuning the i_{SC11} , i_{SC12} , $i_{current_11}$, and $i_{current_12}$, various stimulation waves will be delivered to Electrode array via a lead. To meet the flexible application demand, the proposed SCS system provides four independent stimulation wave outputs.

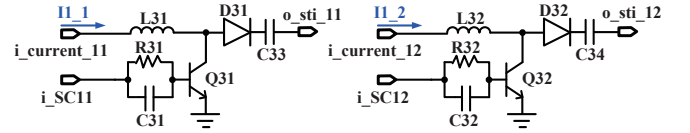


Fig. 4. Schematic of Stimulation wave generator 1

III. MEASUREMENT AND IMPLEMENTATION

The proposed SOC is carried out on silicon using the TSMC (Taiwan Semiconductor Manufacturing Company) standard 0.18 μ m CMOS technology. The the proposed SCS system including the SOC die photo is illustrated in Fig. 5. Fig. 6 shows the packet modulation and LSK demodulation on External Coil, which is measured using Tektronix AFG3252 oscilloscope. The measurements of packet demodulation and LSK_en are illustrated in Fig. 7. The LSK_en is pulled high when the packet from the ASK demodulator passes the CRC verification. Fig. 8 shows the stimulation wave on nerves. The stimulation wave, o_{sti_1} , is the differential signal between o_{sti_11} and o_{sti_12} , where o_{sti_11} and o_{sti_12} are 8.59 V and 9.65 V, respectively.

Performance comparison with a commercial SCS system is tabulated in Table I. The proposed SCS prototype attains longest recharge interval using a 900 mAh Li-ion battery. The data rate and the RF band of the carrier wave are, respectively, 200 bps (bit per second) and 2.0 MHz. Besides, the setting range of the proposed SCS prototype is more flexible than other existing commercial SCS systems.

IV. CONCLUSION

A prototype of a one-time implantable SCS system is proposed in this paper. To reduce the cost of SCS peripherals such as the wireless charger, the packet and power can be transmitted by an inductive link by using the duplex ASK-LSK technique via the inductive link. A rechargeable battery is adopted to store the excess power to extend the life time in Internal Module. Compared with the commercial SCS system, the proposed SCS system has a longer recharge interval.

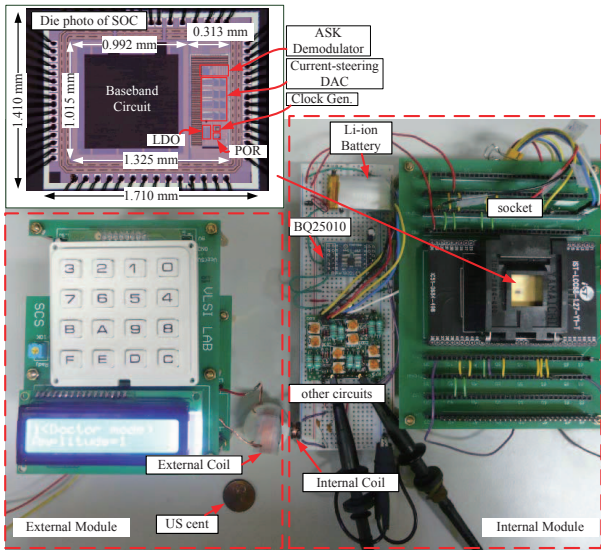


Fig. 5. Photograph of the proposed SCS system

TABLE I
COMPARISON OF THE COMMERCIAL SCS SYSTEM

Device	proposed	Medtronic(*)
Stimulation frequency (Hz)	2 ~ 150	2 ~ 130
Duration of stimulation (ms)	1 ~ 75	N/A
Storage temperature (°C)	-18 ~ +52	-18 ~ +52
Amplitude (V)	0.0 ~ 10.5	0.0 ~ 10.5
Pulse width (μ s)	60 ~ 450	60 ~ 450
Stimulation type	voltage	voltage
Recharge interval (days) (operation in max. power dissipation)	2.13	1.5
Sleep/Charge/Stimulate mode	Yes	Yes
Rechargeable Battery supported	Yes	Yes

* Medtronic RestoreADVANCED 37713

Moreover, the proposed SCS system has a flexible setting range for the generated stimulation waves to meet different stimulation demands.

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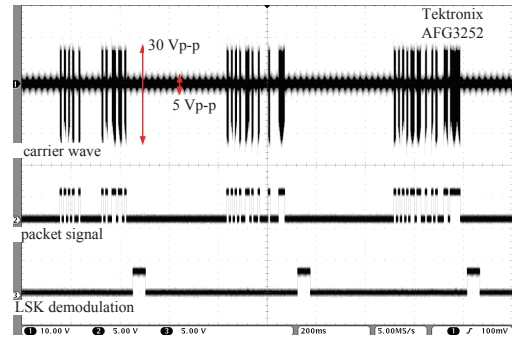


Fig. 6. Measurements of the packet modulation and LSK demodulation

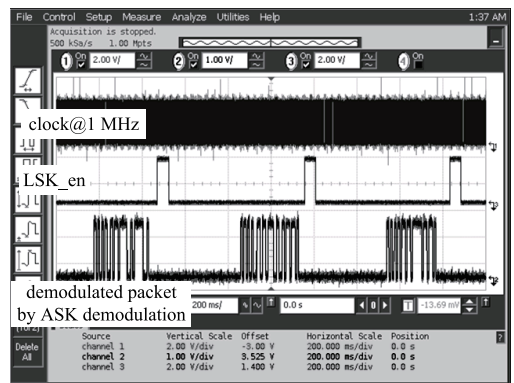


Fig. 7. Measurements of the internal clock, the packet demodulation, and LSK_en

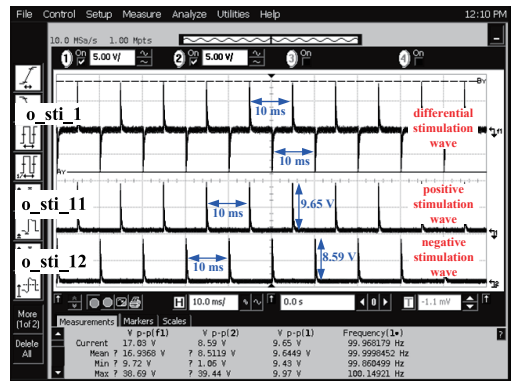


Fig. 8. Measurement of the stimulation wave generator

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