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## Redundant safety features in a high-channel-count retinal neurostimulator

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### Abstract

Safety features embedded in a 256-channel retinal prosthesis integrated circuit are presented. The biology of the retina and the electrochemistry of the electrode-tissue interface demand careful planning and design of the safety features of an implantable retinal stimulation device. We describe the internal limits and communication safety features of our ASIC, but we focus on monitoring and protection circuits for the electrode-tissue interface. Two independent voltage monitoring circuits for each channel measure the electrode polarization voltage at two different times in the biphasic stimulation cycle. The monitors ensure that the charged electrode stays within the electrochemical water window potentials, and that the discharged electrode is within a small window near the counter electrode potential. A switch to connect each electrode to the counter electrode between pulses protects against a wide range of device failures. Additionally, we describe work on an active feedback system to ensure that the electrode voltage is at zero.

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## Keywords

Biomedical engineering; biomedical electrodes; integrated circuit design; retinal prosthesis; retinal implant

## I. Introduction

The development of visual prostheses for the blind is being pursued by several companies and research groups throughout the world [1]-[8]. These devices hold the hope of restoring some useful vision to patients with diseases that cause degeneration of the outer retina. Two of these diseases, age-related macular degeneration and retinitis pigmentosa, affect tens of millions of people worldwide. Many visual prostheses use a camera external to the body to collect images, and use a small device, comparable to a smartphone, to process those images down to a small number of pixels that effectively convey the images. These reduced images are then transmitted to an implanted device, which electrically stimulates retinal ganglion cells via an array of microelectrodes. The patient can see a low-resolution, pixelated view of his surroundings, potentially sufficient for basic navigation and object recognition.

In the last several years, a few groups have conducted clinical trials in blind subjects, and those subjects have been able to perform simple visual navigation and recognition tasks. Of the prosthesis in clinical trials, the most advanced device with individually-addressable electrodes is Second Sight's Argus II, with 60 channels [2]. Another device in clinical trials, produced by German company Retina Implant AG, enabled a patient to read large text one week after implantation [5]. The Retina Implant device uses 1500 non-configurable photodiode-electrode pixels, with wires delivering power to the chip. Our group performed short-term retinal stimulation trials on six blind volunteers between 1998 and 2000, showing that subjects can see individual spots and lines within an hour of electrode implantation [9]. But while these early clinical results provide a proof-of-concept for these types of devices, it is thought that larger numbers of independent channels are needed, which has spurred our group and others to develop higher-channel-count devices [6]-[8].

With higher numbers of stimulation channels comes an increased concern about stimulation safety [10]. Specifically, long-term electrochemical safety at the electrode-tissue interface is a concern, and larger numbers of stimulation channels make it difficult for a centralized monitoring system to keep track of voltages at each electrode. We have addressed this electrode-tissue electrochemical concern with several circuit design innovations. We have added two independent voltage monitors on each stimulation channel to ensure that the electrode voltages do not exceed specified limits on every stimulation cycle. We are also developing feedback circuits to prevent potentially dangerous residual voltage buildup at the electrode-tissue interface.

## II. Circuit and System Architecture

### A. 256-Channel Retinal Prosthesis

The Boston 256-Channel Retinal Implant comprises an external transceiver and an implanted hermetic neural stimulator. When clinical trials are begun, an external camera and

portable image processor will be added to enable more independent use by patients. The wireless power and data drive a custom integrated circuit enclosed in a hermetic titanium case with a ceramic high-density feedthrough. The chip stimulates retinal tissue based on the received image data, via a thin-film microfabricated electrode array, using 256 independently controlled current source channels. Figure 1 shows the retinal implant concept, the 256-channel prototype implant on an enucleated human eye, and details of the high-density feedthrough.

## B. 256-Channel ASIC Design

The central component of the retinal prosthesis is our custom ASIC, fabricated in an IBM 0.18 $\mu\text{m}$  high-voltage process, which manages communication, control, and retinal stimulation. The ASIC measures approximately 5mm  $\times$  5mm, and a close-up die photograph is shown in Figure 2. A block diagram of the ASIC is shown in Figure 3, and its circuits consume approximately 100 $\mu\text{W}$  in standby mode, with a targeted maximum power consumption of 30mW during retinal stimulation. The most relevant parts of the high-channel-count ASIC for this paper are the independent current drivers and the electrode safety monitoring module. The current drivers, shown in Figure 4, are cascoded, high-voltage current sources, controlled by low-voltage switches. They are capable of delivering currents from 0 to 126 $\mu\text{A}$  in 1  $\mu\text{A}$  steps from a power supply of either  $\pm 4\text{V}$  or  $\pm 8\text{V}$ , with stimulus duration from 17.7 $\mu\text{s}$  to 4.5ms. The ASIC is capable of driving any subset of electrodes during one cycle of stimulation, and this flexibility can be used, for example, to steer currents by sinking cathodic stimulating current through one electrode while sourcing smaller anodic currents through several neighboring electrodes, which act as counter electrodes. The electrode monitoring block includes two independent monitoring circuits for each channel, which will be described in greater detail below.

## III. Stimulation Safety Features

Both the underlying biology of the retina and the electrochemistry of the electrode-tissue interface require careful consideration when designing safety systems for a retinal prosthesis. As a result, our retinal stimulation ASIC has a number of safety features. The chip has built-in hardware stimulus charge limits to prevent overdriving the electrodes or tissue by human error, a comprehensive power-on self-test system, configuration pins to lock out chip testing modes during clinical operation, and error checking on data transmission with 32-bit cyclic redundancy checks, which reduce data error rates to  $2^{-10}$ .

One particular concern is the polarization of the electrode-tissue interface. If that interface is driven outside the electrochemical water window of -0.6V to +0.8V, charge injection occurs in the form of oxidation or reduction of water, which can be biologically damaging and mechanically damaging to the electrodes [11].

Measuring the electrode-tissue interface voltage is a challenging problem [12]. Our prosthesis uses sputtered iridium oxide film (SIROF) electrode sites, which have the benefit of allowing very high charge densities (exceeding 1mC/cm<sup>2</sup>) with reversible electrochemical reactions, but which have the possibility of suffering mechanical failure if the interface is repeatedly driven outside the water window. However, due to the non-linearity and

distributed nature of the electrode impedance, it is very difficult to measure the electrode-tissue interface while the stimulus current is on. Therefore, we measure the electrode polarization in the middle of the biphasic current pulse, during the interphase interval (Wip in Figure 5).

### A. Electrode Polarization Monitoring and Shorting

The ASIC includes two electrode voltage monitors for each current driver. A functional schematic of the voltage monitor circuits is shown in Figure 6. The monitors check the electrode polarization at two different points in time, during the interphase interval (Wip), when the electrode is fully polarized for a given stimulation, and between biphasic stimulus pulses, when the electrode polarization should nominally be zero. During the interphase interval, the voltage monitor ensures that the charged electrode during a zero-current state is still within the electrochemical water window. If an electrode has exited this window, a signal is sent to the controller and that electrode is disabled and shorted to the current return counter electrode. After the end of a balanced biphasic pulse, the electrode voltage should nominally be zero. However, as we have described in [13], a residual voltage is left on the electrode even after a perfectly balanced biphasic current pulse, due to leakage in the electrode-tissue interface. Therefore, a switch is used to short the electrode to the counter electrode for some time. The second voltage monitor ensures that the electrode voltage between biphasic pulses is within a very small window, typically  $\pm 0.1\text{V}$ . This protects against a variety of failures, including failure of the shorting switch, gross charge mismatch (e.g., failure of one current polarity), and a short developing between an electrode and a power supply. A failure detected by this monitor sends a message to the external circuitry, disables the electrode, and forces the prosthesis to reset. The timing and voltages of these monitoring circuits is summarized in Figure 5. Results from the water window monitor circuit are shown in Figure 7. The top and middle waveforms are the electrode current and voltage, respectively, under normal operating conditions. In the bottom waveform of Figure 7, the safe window for the monitor is set very conservatively, to a very small value, triggering the system to disable and short the electrode. Waveforms from chip testing showing the timing of the electrode shorting waveform are shown in Figure 8.

These monitors protect both the tissue, which can be damaged by irreversible electrochemical reactions related to neural stimulation, and the electrodes, which can be physically damaged from repeated driving of irreversible electrochemical reactions.

### B. Electrode Polarization Feedback Control

A second method to control the electrode-tissue interface potential is being developed by our group. If the electrochemical leakage in the electrode-tissue interface is known to result in a residual voltage on the electrode [13], then we should use feedback to prevent the residual voltage from occurring. An active anodic feedback control system senses the residual voltage after one biphasic cycle and adjusts the timing of the next anodic current phase to eliminate the residual voltage completely. The results of this system are shown in Figure 9.

## IV. Conclusion and Future Work

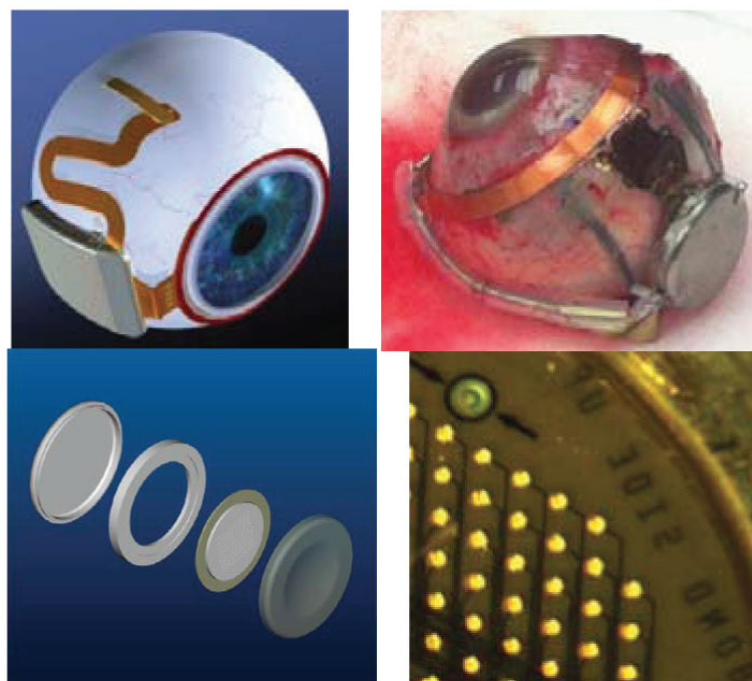
The Boston Retinal Implant Project has developed a highly-configurable 256-channel neural stimulation ASIC to serve as the core of a hermetic high-density subretinal prosthesis. The chip has flexibility to allow a wide range of stimulation currents and phase durations, and the flexibility to drive arbitrary currents through arbitrary electrodes to enable current steering in the tissue. Most importantly, the ASIC includes several redundant safety features, primarily relating to the electrode-tissue interface. These circuits, both the monitors and the shorting switches, will be further tested in preparation for retinal prosthesis clinical trials.

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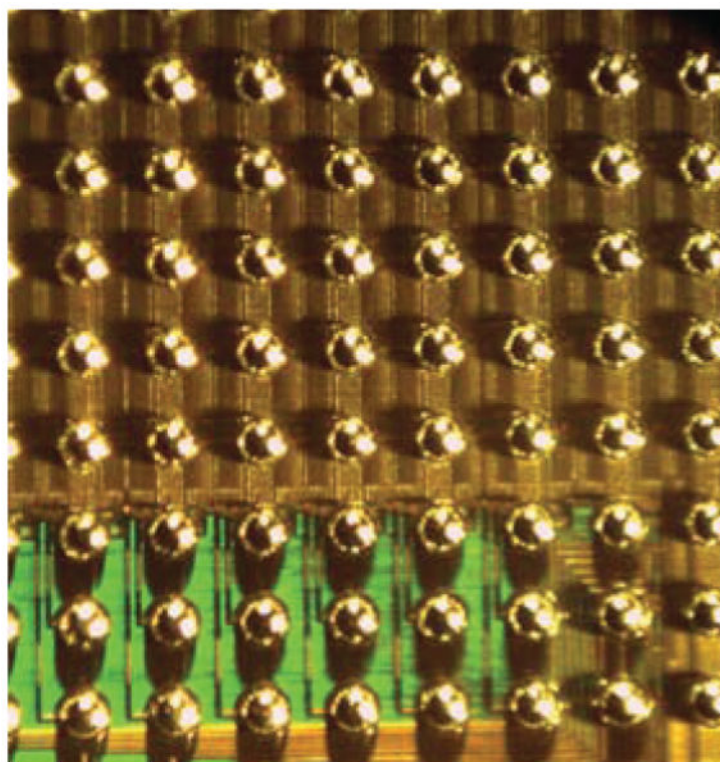
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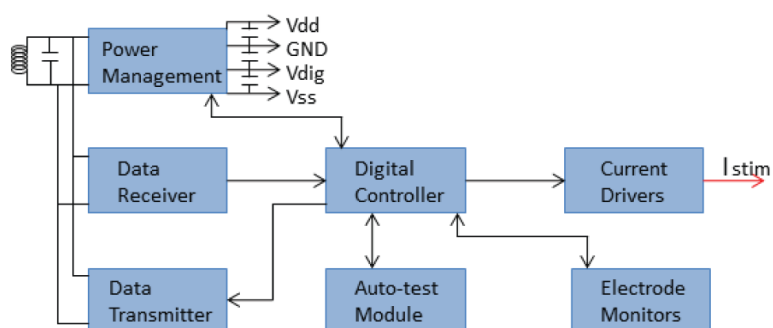


**Fig. 1.** 256-Channel Boston Retinal Prosthesis. Top row shows the retinal implant concept and an early prototype implant on an enucleated human eye. Bottom row shows the hermetic package and high-density feedthrough.



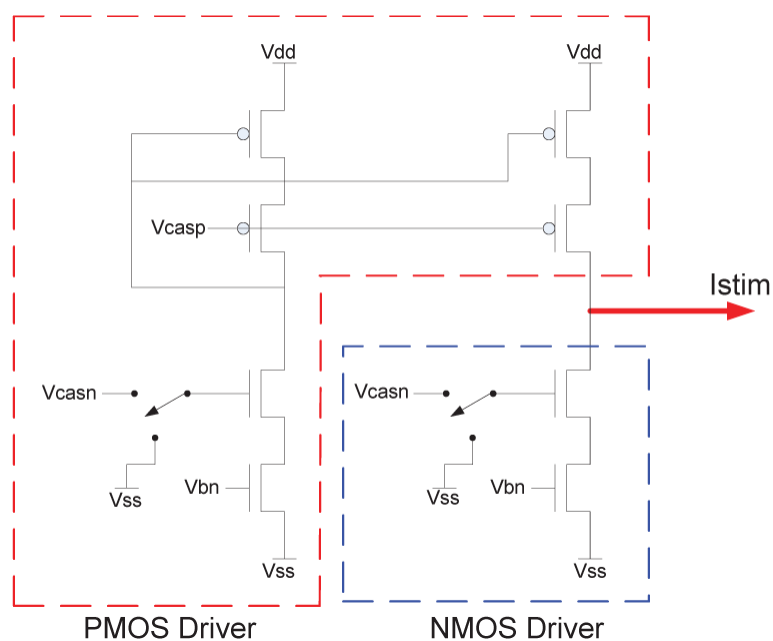


**Fig. 2.**  
Close-up of gold ball-bumped high-channel-count retinal implant ASIC.

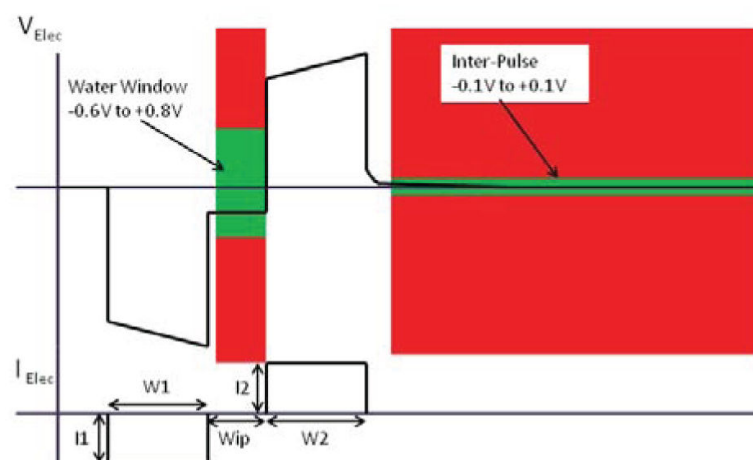


**Fig. 3.**  
Architecture of the retinal prosthesis ASIC



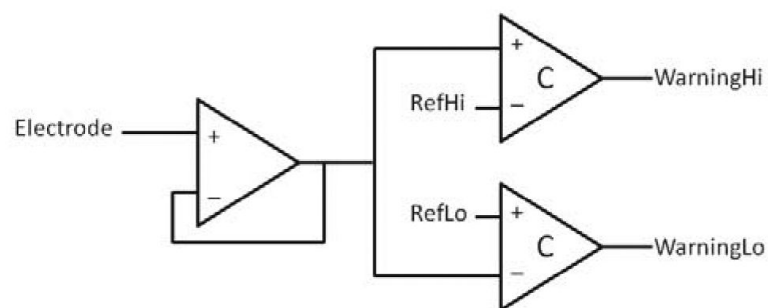


**Fig. 4.**  
Electrode current drivers, using low-voltage switches to drive high-voltage cascode current sources.



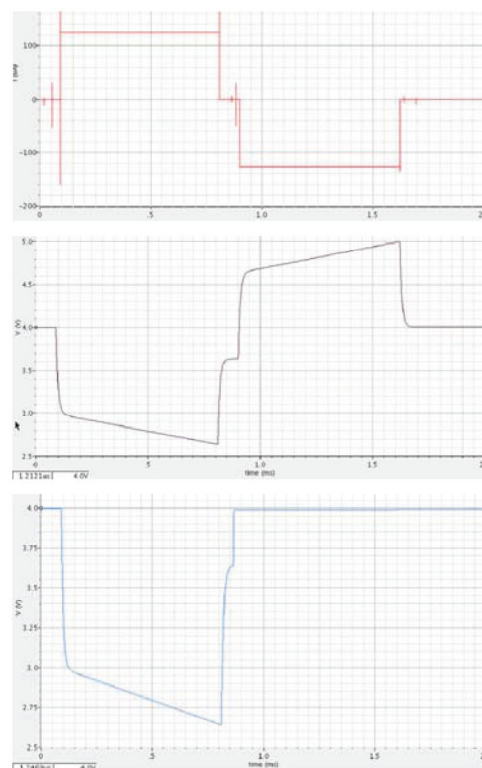
**Fig. 5.**

Electrode monitor voltage limits and timing. The voltage of a charged electrode must be within the electrochemical water window, and the voltage of a discharged electrode must be very close to zero.

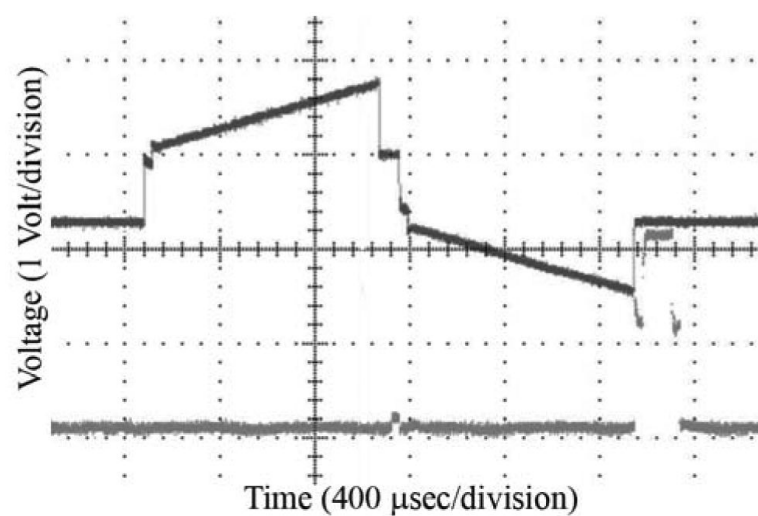


**Fig. 6.**

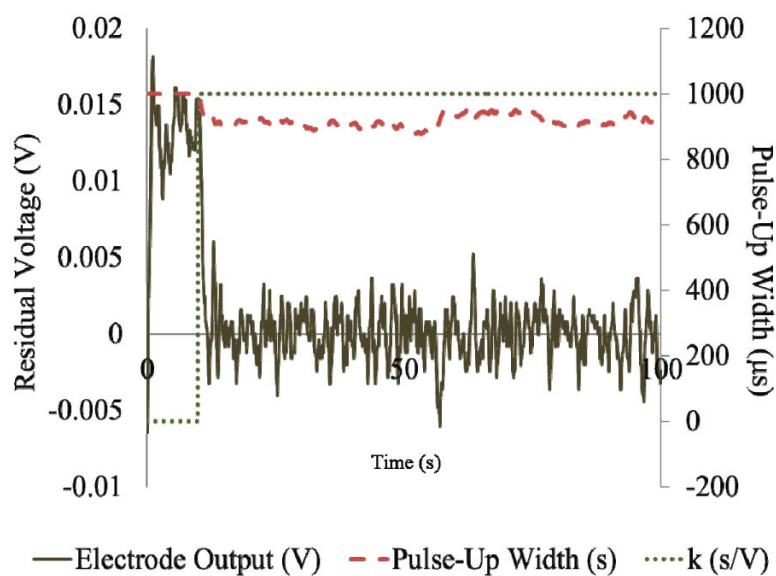
Electrode voltage monitor circuit. The electrode voltage is buffered and compared to high and low threshold voltages, and raises warnings if the voltage surpasses the thresholds.



**Fig. 7.** Safety monitor testing. Top – Current waveform. Middle – Voltage waveform with normal water window monitor settings. Bottom – Voltage window with very conservative water window monitor settings, showing disabling of the electrode.



**Fig. 8.** Electrode shorting switch testing. Chip testing with a mock resistor-capacitor electrode model. The lower waveform is the gate drive signal for the grounding switch.



**Fig. 9.**

Results of electrode polarization feedback control circuit. With the circuit off, a residual voltage is seen (solid black trace). When the feedback is turned on, the residual electrode voltage drops to zero.