Active Charge Balancing for Cardiac Stimulation

Maci Miri

Senior Project

Electrical Engineering Department

California Polytechnic State University

San Luis Obispo

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Abstract

Worldwide, there are about 3 million people who have pacemakers, with 10,000 new implantations of ICD’s each month. [heart.org] Due to the gravity and importance of the function that ICD’s provide, these devices must be extremely reliable and highly effective. However, because of the high tolerances of IC manufacturing, stimulation circuits for pacemakers may be slightly unmatched and over time, may have a net DC charge applied to the tissues in the heart. Extra charge pumped into body tissues is dangerous for the patient’s health; the pH of the tissue can be raised and corrosion of the stimulating electrodes may occur. This project entails the study and design of methods that allow balanced stimulation of cardiac tissue. Due to the expense of manufacturing integrated circuits, this project aims only to have representative simulations of our circuit solutions. By using dynamic current matching, we hope to cancel out the DC charge inadvertently applied to the heart in a cost effective manner.

Acknowledgements

I’d like to thank Bridget Benson for her help and supervision throughout the development of the balanced stimulator.

I’d like to thank Tina Smilkstein for lending me her knowledge and experience in IC circuits as we analyzed different possible solutions.

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Table of Contents

List of Figures

List of Tables

Chapter 1: Introduction

For people who may have ventricular arrhythmia or congenital heart diseases that may cause sudden cardiac arrest, a device is needed to deliver an electric shock to restart the heart or control it to beat normally and safely. Newer ICDs (Implantable Cardioverter Defibrillators) have the ability to both shock the heart back to function if it stops as well as function as a pacemaker and regulate normal heartbeats in these patients.

In order to maintain the integrity of the tissues and the electrodes, the net charge applied to the heart over time must be zero. If this is not the case, the imbalance of charge in the tissue can alter the pH of the flesh as well as corrode and damage the electrodes of the ICD itself, necessitating further surgery. A biphasic pulse stimulation scheme is applied to satisfy this requirement (shown in Figure 1). First, a negative current pulse is applied to the heart, followed by a positive pulse of the same magnitude. It’s extremely important that the negative and positive pulses have exactly the same duration and magnitude so that they, in effect, cancel each other out. The negative pulse must come first, so as to avoid hyperpolarizing nearby nerve cells and interfering with nerve signal transmission. Then, the positive pulse can cancel out the change in charge caused by the initial negative pulse.

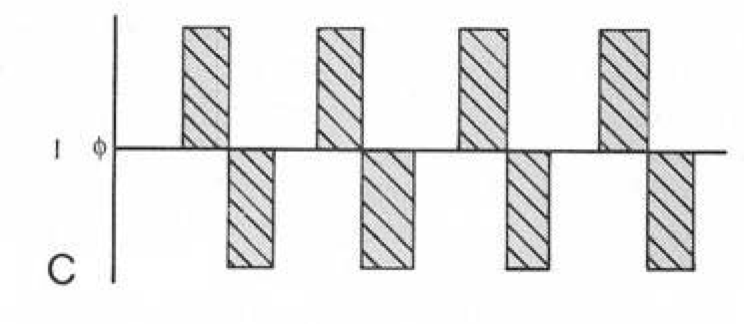

Figure 1: Rectangular symmetric biphasic pulsed current

Currently, the industry-standard method to eliminate this charge imbalance is to use large, high quality capacitors placed in series at the end of each electrode. However, you need one of these capacitors for each electrode. While cardiac stimulation generally doesn't use more than 2 or 3 electrodes, other types of stimulation such as retinal stimulation or neural stimulation may have a great many electrodes. In either case though, these AC coupling capacitors make it hard to scale down both the size and the cost of the circuit. This is why an actively charge-balanced IC solution is desired. Being able to replace the large AC coupling capacitors with a small active solution would allow smaller, cheaper devices.

This project presents an actively controlled solution to the problem of applying identical negative and positive pulses to a cardiac load. Using a method called dynamic current matching, we are able to accurately match both phases of stimulation and negate the harmful effects of net DC charge over time.

Chapter 2: Requirements/Specifications

The Active Charge Balance must meet very strict requirements in order to be meet FDA regulations. These requirements, along with those desired by St. Jude Medical, are listed in Table 1 below.

Table 1: Requirements for active charge balance

Number	Requirement	Justification
1	<100 nA net DC current (~10 nA desired)	100 nA is the legal FDA threshold to limit damage to tissue, but lower is better
2	Cardiac load = 550 Ω	The resistance of the cardiac tissues is about 500 Ω. The switches and circuitry used for control add about another 50 Ω.
3	Electrodes add two 3 uF capacitors in series with the cardiac load	The interface between the electrode and the tissues of the flesh add parasitic capacitances
4	Be able to handle voltage spikes up to 18 V	The expected voltage is about 14 V, but 18 allows a safety margin.
5	Stimulation current = 25 mA	This is the desired stimulation current – set by St. Jude Medical
6	Biasing currents must be in the uA range (keep power consumption of control circuitry insignificant)	These biasing currents must be small enough to not comprise a significant portion of the power for the ICD.

This project will focus on the pacemaker feature of these ICDs. While some models feature wireless charging, most ICDs must be replaced every time the battery runs out, on average every 3 to 5 years. Because the power consumption can so strongly affect the quality of life and financial costs for a patient, the charge balanced circuit must be extremely energy efficient.

Figure 2: Example of a common ICD. Can and electrodes are shown

While this sounds great theoretically, in practice, it's very difficult to actually have stimulation that is so well matched between the negative and the positive pulses. The process variation of IC manufacture makes it very hard to predict exactly how a transistor will operate and exactly how much current it will pass through at any given set of voltages. This can lead to a net imbalance in the charge imparted to the cardiac tissues. The FDA limit for this imbalance is 100 nA because this is the level at which damage to the tissue begins to occur. For this project however, we'd like to reach a target of ~10nA, in order to guarantee safe operation over a wide variety of use-cases.

In Figure 3 below, it can be seen that an imbalanced application of the current pulses will causes charge buildup on the electrodes, leading to a net voltage that varies over time.

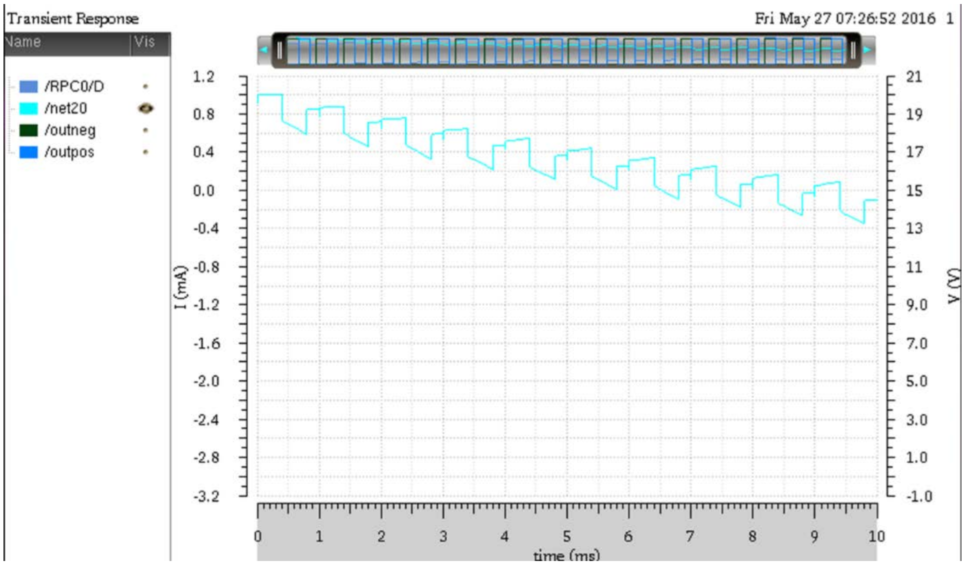

Figure 3: Imbalanced Stimulation

Chapter 3: Design

The main technique our circuit uses is dynamic current matching. Dynamic current matching allows us to run a current through our current source and our current sink and then “save” the voltages necessary to maintain this current, thereby making sure the negative and the positive pulse are of the same magnitude.

Here is a quick overview of how dynamic current matching works:

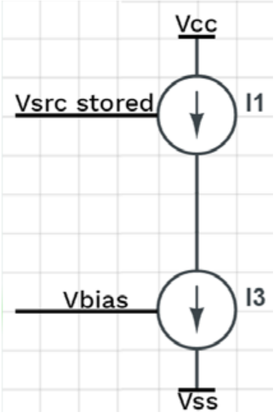

Figure 4: Sampling phase

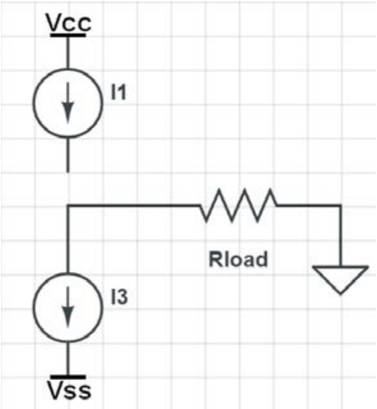

Figure 5: Negative output phase

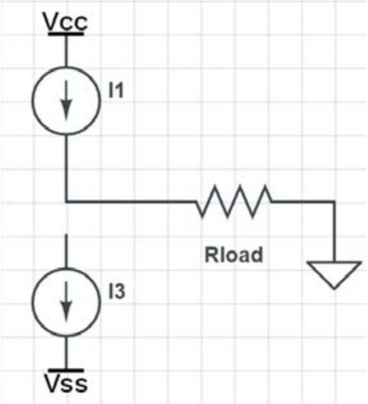

Figure 6: Positive output phase

In the Sampling Phase of Figure 4, the lower current source I3 biases the top current source I1, and the voltages that allow this to occur are saved across a capacitor. In the Negative Output Phase of Figure 5, the current source I1 is disconnected so that the load may be connected and a current drawn from it. In the Positive Output Phase of Figure 6, the current source switches are rearranged so that the ‘saved’ configuration of voltage may then be applied to the circuit, allowing current flow in the opposite direction of the same magnitude.

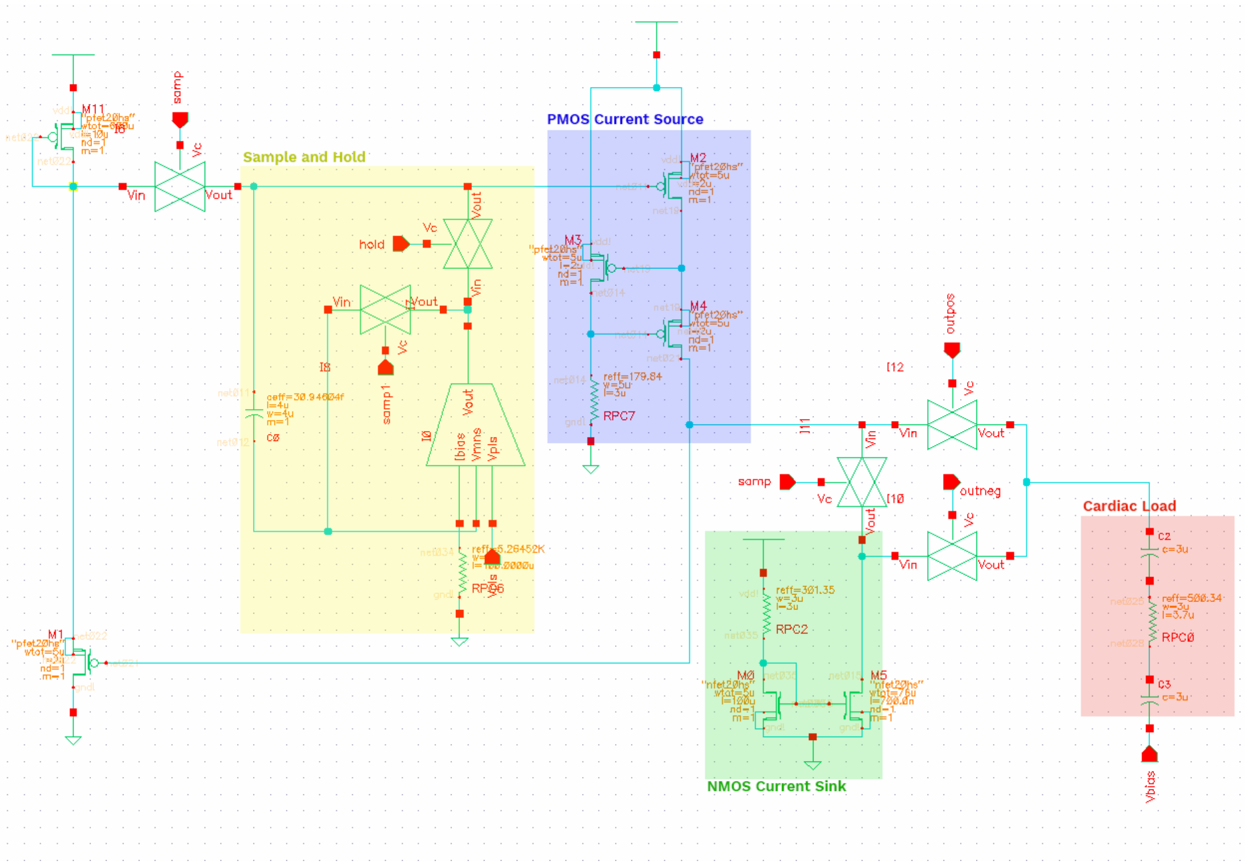

Figure 7: Biphasic stimulating circuit shown with current source and sink

In our stimulation, there are 4 phases:

1) Precharge
2) Negative pulse
3) Positive pulse
4) Wait/Short interval

As previously mentioned, the precharge phase allows us to run a single current through a series combination of the pmos current source and the nmos current sink. The nmos current sink is the driving component in the circuit, and it is what sets the gate voltages necessary for the pmos current source to be able to supply the same amount of current. The gate voltage, Vp, is automatically set via the feedback network shown in Figure 8 below to the correct value to allows that current to flow through it This gate voltage for the current source is held across a capacitor and transconductance amplifier combination. The capacitor allows us to hold the necessary voltage until we need it during the positive pulse output phase. Therefore, when we disable the biasing circuitry, the pmos is still able to reproduce the set current because its controlling voltages have been held.

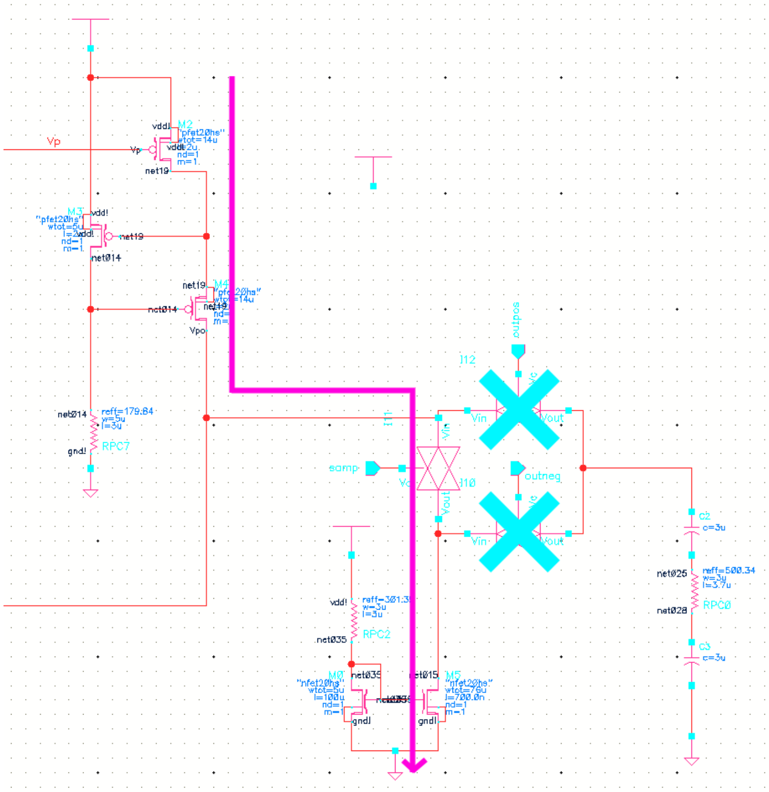

Figure 8: Presampling phase

After the circuit settles in the precharge state, the sampling transmission gates and the pmos current source are disabled (shown by the large blue X's), and the nmos current sink is enabled. Now, the current source can pull current from the load, thereby creating a negative pulse. This action is shown in Figure 9 below. However, current sources in the real world cannot be ideal, the ending terminal for the load must be at a higher potential than ground for proper operation. This will slightly change later when we modify the circuit to apply current to a floating load.

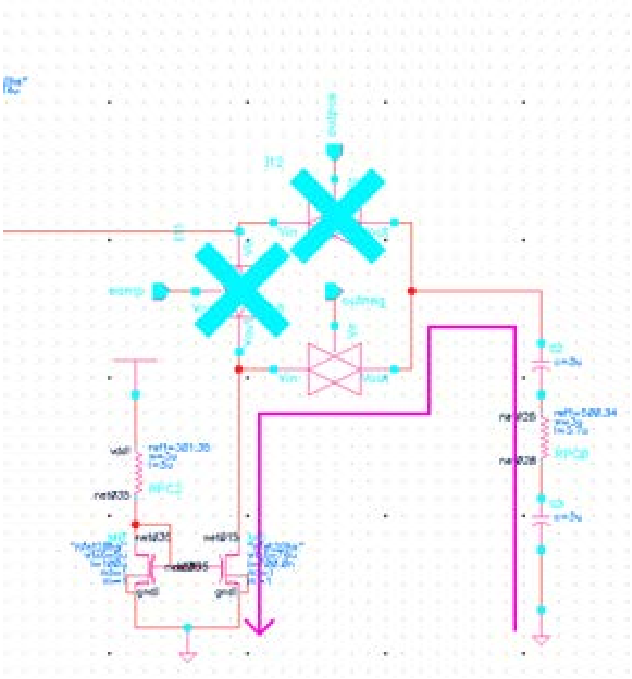

Figure 9: Controlling voltages in negative pulse phase

The negative pulse is applied first because if we did the opposite, the positive current would hyperpolarize the nerve cells in the area and inhibit action potentials. This results in a refractory period of up to approximately 2 ms where the nerve cell is unable to transmit. However, if the negative pulse is applied first, this effect does not occur. The subsequent positive pulse then, can restore the charge displaced by the negative pulse, fulfilling the zero net dc charge imparted specification of our circuit.

For the positive pulse to be applied, the control signals must switch and disconnect the nmos current sink (shown by the large blue X's) and allow through the pmos current source. Even though this part of the circuit was previously disconnected, it is still able to source an identical current to the nmos current sink because it's gate voltage has been held across the capacitor. Because in the real world capacitors have some leakage, the transconductance amplifier is used to restore the lost charge across the capacitor during its hold state. This further helps keep the current constant throughout the multi-phase process. Figure 10 below shows the path through the pmos current source to the load.

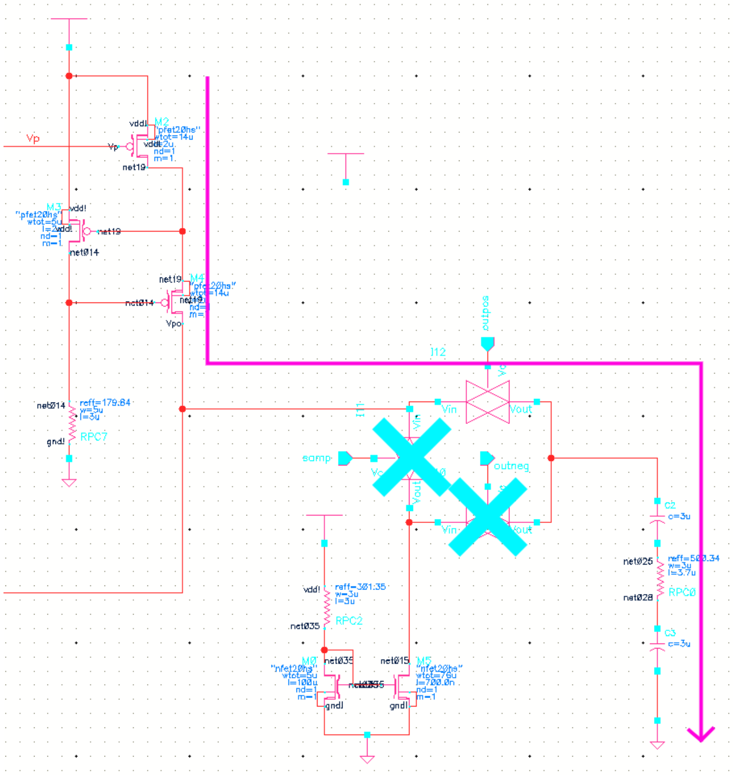

Figure 10: Positive current pulse path

After both pulses have been applied, there is an interpulse gap where the load can be shorted to ground to remove any charge that could have been built up through minute differences in the two pulses. This short phase allows the circuit to settle before the next phase of stimulation begins.

In some models of pacemakers, though, the cardiac load is a floating load, rather than a grounded one. Two or more electrodes can connect on either end of the stimulation sites and work in tandem. This full circuit is shown in Appendix A. In this circuit, a mirrored version of the original circuit has been placed in order to drive the current from the other side as well. However, on the right side, the control signals for the negative and positive output phases have been switched, so as to create a push/pull type action. When the left side sinks the negative current, the right side sources the same current. When the left side sources the positive current, the right side sinks the equivalent current. This allows for a circuit that is more readily adaptable to modern systems.

Chapter 4: Testing

To test this circuit, the performance was analyzed using Spectre simulations at each revision. The results for the current floating load revisions are shown in Figure 11 below.

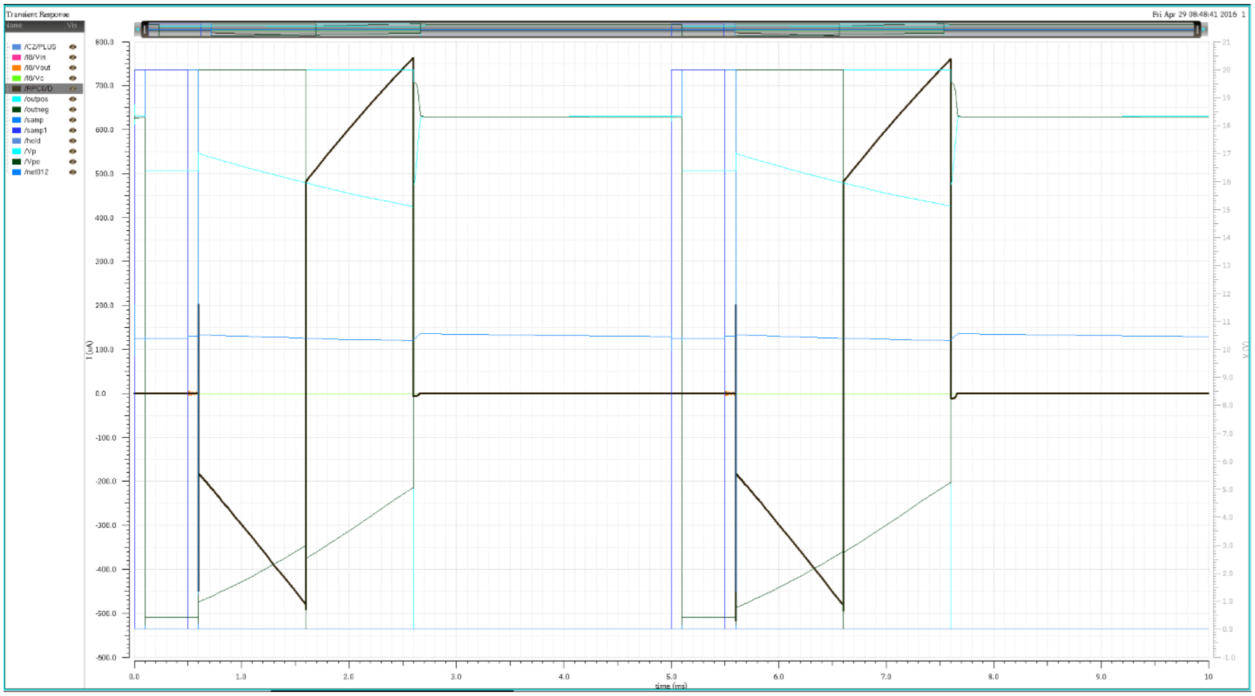

Figure 11: Simulation current through the floating load (dark black)

It can be seen that the negative and positive pulses are firing at the correct times and in the correct fashions. However, two issues I'm currently dealing with are the ramp up in current over time through the load, as well as low output current. The circuit is close to completion, I believe some transistors must just be sized differently.

There is a value, Gmin, which has to do with the conductance of the components in the circuit. In practical terms, this value will affect how quickly the components will leak current when the transistors or transmission gates are supposed to be in the off state, or when the capacitor is supposed to hold the Vp biasing voltage. When I decrease this value in order to obtain a better functioning circuit, we are able to obtain the following:

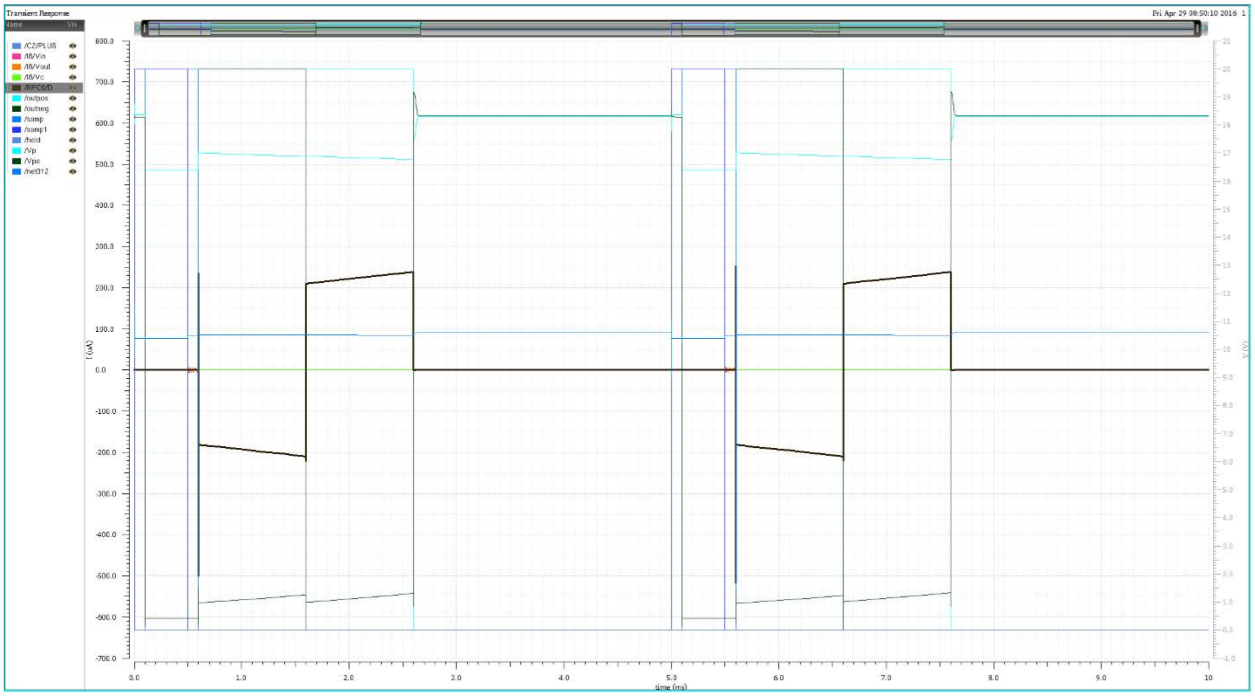

Figure 12: Simulation current with modified Gmin

In Figure 12 above, the circuit is able to provide better functionality. The negative and positive pulses are matched more evenly; therefore, the balancing will better be able to ensure that no charge gets inadvertently administered to the cardiac tissue. In practice, however, this value would relate to the actual process used to manufacture the transistors on the silicon wafers. So a lower leakage tolerance would translate to significantly more expensive fabrication processes.

Table 2 below restates the requirements of the project and how this implementation is able to satisfy them.

Table 2: Requirements met

Number	Requirement	Requirement met?
1	<100 nA net DC current (~10 nA desired)	Yes, under the right conditions, the negative and positive pulses can be almost perfectly matched.
2	Cardiac load = 550 Ω	Yes, the load was able to be modeled appropriately.
3	Electrodes add two 3 uF capacitors in series with the cardiac load	Yes, this capacitance was able to be modeled appropriately.
4	Be able to handle voltage spikes up to 18 V	Yes, the transistors chosen were able to handle up to 25 V.
5	Stimulation current = 25 mA	Yes, this current is able to be obtained by increasing the multiplicity of the transistors in order to match the high current output.
6	Biasing currents must be in the uA range (keep power consumption of control circuitry insignificant)	Somewhat. This implementation used simple current mirrors with resistive loads rather than more complex and power efficient versions to keep implementation simple.

Conclusions

This circuit proves that it’s possible to use dynamic current matching to stimulate cardiac tissue with balanced biphasic pulses. These designs will allow for smaller, cheaper ICDs, which can benefit everyone who has an irregular heartbeat or arrhythmias. The elimination of large AC coupling/DC blocking capacitors will also allow for easier stimulation using many electrodes, such as those schemes used in retinal and neural stimulation.

Future Work:

There are a few key ways in which this circuit could be improved. The current output through the load needs to be higher, but I suspect this will have to do with the transistor dimensions and bias currents currently being used to define functionality of the circuit.

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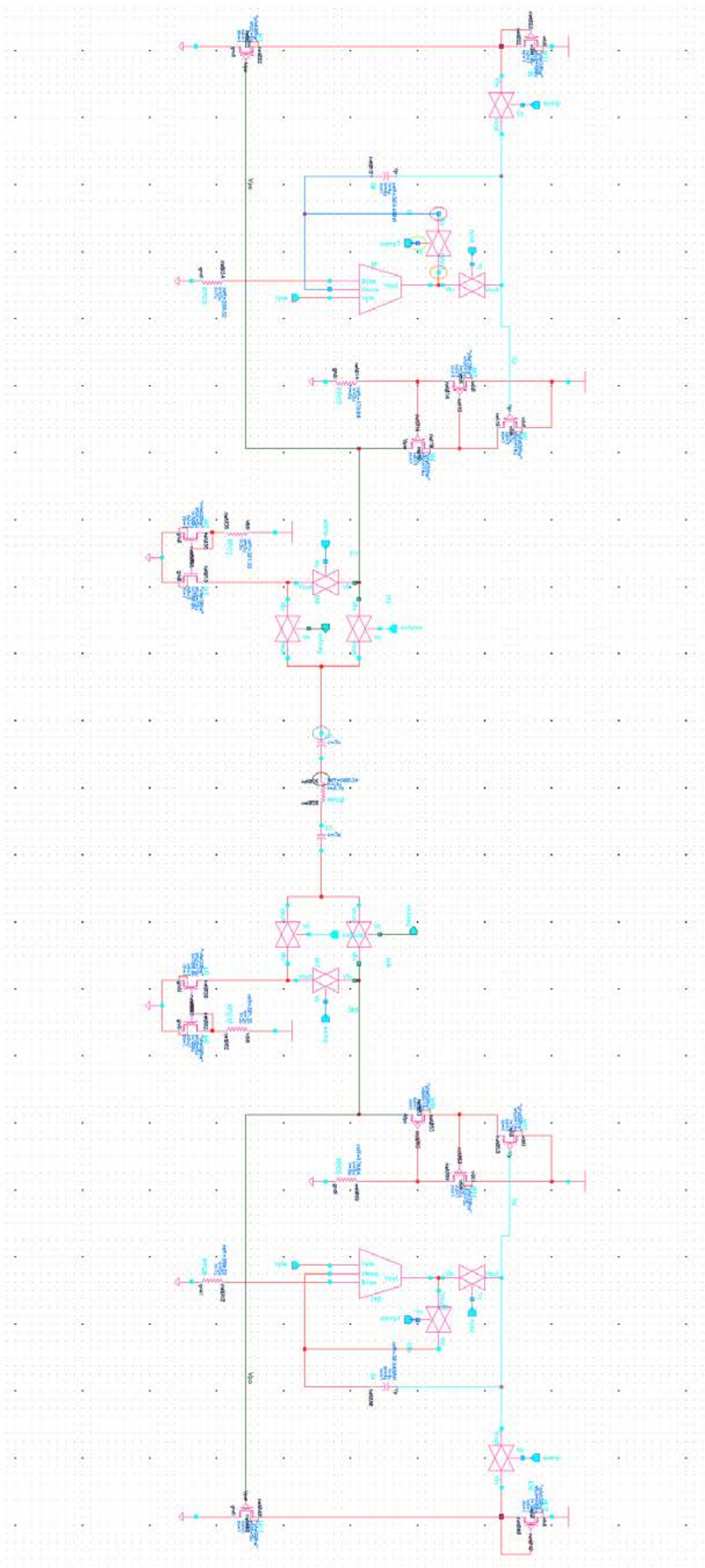
Appendix A: Floating Load Stimulator Circuit



The circuit topology for the floating load stimulator circuit.

Appendix B: Analysis of Senior Project

Summary of Functional Requirements:

This project is capable of supplying an identical negative and positive pulse to a cardiac load with capacitive electrodes using dynamic current matching. This allows imperfections of manufacturing transistors in silicon to be mitigated. The source and sink are matched in a sampling phase before stimulation occurs, and the necessary voltages are ‘saved’.

Primary Constraints:

One of the most significant challenges to this project was the fact that the stimulation needed to occur at 25 mA of current and the required error was less than 100 nA. The relative difference between these is so small that a measurement solution would have been impractical. Instead, this circuit disregards the minute differences in the charging simulation and instead makes sure that they’re identical so that they’re not applying any net charge.

Economic:

Because this project was conceived with the knowledge that no practical circuit would be fabricated in real life due to the expense, only simulations were needed. Therefore, there is no cost involved with this project.

This project was intended to take 3 months of development, for my last quarter at Cal Poly. While the circuit was constructed and analyzed, additional work could be done to allow for larger stimulation currents.

If manufactured on a commercial basis:

This project is an internal project for St. Jude Medical company. There are approximately 10,000 new ICD’s each month, so this circuit could potentially be implemented in all of these, given some refinement.

Environmental:

This design would be implemented in a silicon wafer, so the environmental impact of silicon mining may apply. However, silicon is the most common element in the planet’s crust.

Manufacturability:

This design is difficult to implement in real life. It’s not easily implementable by hobbyists because it costs millions of dollars to fabricate these wafers.

Ethical

As far as I can tell, there aren’t any ethical issues with the Active Charge Balancing Stimulation project because it’s aim is to help save lives.

Health and Safety:

The risks associated with a project like this are great. Because the project is controlling a human being's heart, there is a lot of reliability testing that must go into it to make sure that the design works as intended. Any mistake or defect in the system could be fatally catastrophic if there aren't safeguards.

Social and Political:

Thankfully, ICD's and pacemakers are a socially acceptable solution to the problems that arrhythmias produce. As such, this project that aims to improve ICD performance should have no issues with social and political perceptions.

Development:

In order to get the fine control of each transistor that is necessary for a design in silicon, this project had to be done in Cadence Virtuoso. This isn't a program that I'd used before, but learned as I continued working on the project. Also, Spectre was used to run the simulations of how the circuit would function under various inputs and loads.