Circuit Design Considerations for Power-Efficient and Safe Implantable Electrical Neurostimulators

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Abstract— **This paper presents the main circuit design considerations for power-efficient and safe implantable electrical neurostimulators. Related to medical applications, low-frequency (LF) stimulation for generating new action potentials and kilohertz-frequency alternating current (KHFAC) for blocking unwanted neural activity are introduced, respectively. For implantable medical devices, the choice of energy source type is important as it has an influence on the total size of the device and device comfort, thereby affecting the quality of life of the patients. In order to lengthen the lifetime of the stimulator, power-efficient designs using the ultra-high frequency (UHF) pulsed technique are proposed. To avoid tissue damage and electrode degradation caused by residual charge on the electrode-tissue interface (ETI), charge balancing (CB) techniques are adopted. Active CB control is shown to be a promising method both for LF and KHFAC stimulation.**

Keywords—implantable electrical neurostimulator, power efficiency, safety, active charge balancing.

I. INTRODUCTION

Neuromodulation technologies are widely used for the treatment of various diseases caused by neural disorders. They can provide patient-tailored therapy with less side effects than conventional medicine [1]. Neural activity manifests itself, a.o., as changes in the membrane voltage [1]. The principle of neuromodulation is to change said membrane voltage to excite or inhibit nerve cells by means of pulses with specific properties, such as pulse shape, pulse repetition frequency, pulse duration, pulse magnitude, etc.

Until now, electrical, optical, ultrasonic and magnetic forms of stimulation have been shown to elicit certain responses from nerve cells, but electrical stimulation is the most common method [2]. Electrical stimulation uses electric charge to generate the required electric field to depolarize or hyperpolarize the cell membrane. This electric charge can be built up by means of controlling any electrical quantity, viz. charge, current or voltage in the stimulation site [2].

According to their working principle, there are mainly two kinds of application fields for implantable electrical neurostimulators. One, commonly employed for vagus nerve stimulators, cochlear implants, retinal implants, etc., is to induce artificial neural activation (commonly referred to as neurostimulation) by evoking new action potentials. This is commonly achieved by using low frequency pulses [2], in the range of below or around 100 Hz. The other application lies in the fields of blocking unwanted neuronal activity in cases of urinary retention, chronic pain, etc. This "conduction block", as is commonly referred to, is in most cases achieved through kilohertz-frequency alternating current (KHFAC) stimulation [3].

Batteries have been commonly used as the preferred powering technique for most active implantable devices. More recent technologies are shifting towards wireless power transfer (WPT) methods [4]. These methods allow for the miniaturization of the implants while increasing their functional lifetime, as opposed to the bulkiness and low durability of batteries. The most common techniques can be categorized as: acoustic power transfer (APT) using ultrasound (US), RF far-field power transfer (RF), and near-field inductive coupling (NF) [4].

For neurostimulation, from a power efficiency perspective, it is desirable to have the neural stimulator as close as possible to the target tissue. Besides, power efficiency also determines the size and lifetime of the energy source, and heat dissipation should be minimized to avoid any tissue damage caused by an increased temperature inside the body. To address these issues, a promising method is the UHF current pulsed technique [5], which employs a filter-less DC-DC converter and thereby avoids the need of bulky filtering capacitors for stabilizing the converter output voltage.

Besides power efficiency, the other biggest challenge is safety, which requires stimulation schemes that will not lead to tissue damage and electrode degradation [6]. According to the Shannon criteria [7], the charge per phase delivered to the tissue and residual charge on the ETI should be within specific safety limits. This means that the offset voltage on the electrodes, which is proportional to the residual charge, should stay within a safety window [8]. However, the offset voltage usually goes up during stimulation due to the charge mismatch between the cathodic and anodic phases, and nonlinearities of the electrode-tissue interface (ETI) [9, 10]. For this reason, safety control techniques are necessary to automatically ensure that the offset voltage meets the safety requirements. These available techniques are different for LF stimulation and KHFAC stimulation applications, due to the different stimulation patterns.

The rest of the paper is organized as follows: Section II introduces the powering techniques for implantable electrical neurostimulators. Power-efficiency and safety-control schemes are presented in Sections III and IV, respectively. These are followed by the conclusions in Section V.

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II. Powering Techniques for implantable electrical neurostimulators

The two main approaches to power implantable electrical neurostimulators are batteries and wireless power transfer (WPT) methods. Energy harvesting and scavenging are alternative ways of powering devices, but because they depend on the availability of energy in the environment, they can never be reliable enough for some applications, like most neurostimulators, due the scarcity of available energy [4].

A. Battery

Batteries provide a reliable and constant source of power but at the cost of big size and limited lifetime. Patients need to undergo surgery to replace a new battery when the old one has depleted. This gives a lot of economical, physical and mental burden to patients. In addition to this, batteries contain chemicals and materials that are not necessarily biocompatible, which requires stricter protection and packaging precautions.

B. Wireless Power Transfer (WPT)

Because of the aforementioned limiting factors of batteries, new advancements are pointing at wireless power transfer methods as the most promising alternatives. In principle, there are many ways of wirelessly transferring power inside the body. To determine the choice of WPT method mentioned in Section I, implantation depth, device size, biocompatibility and biostability of the implants are a few design parameters to be taken into account. For example, ultrasonic power transfer has been proven to outperform the other methods, when the implant is located deep (>10 cm) inside the body [4]. On the other hand, the power transfer efficiency of bigger devices implanted close to the surface is higher when an inductive coupling link is used [4], like in the case of cochlear implants.

The efficacy of the stimulation is related to the amount of charge delivered to the tissue [6]. This charge is commonly controlled by setting the duration of a well-known constant energy source. Two examples are constant-current stimulation (CCS) and constant-voltage stimulation (CVS). However, one common disadvantage of all WPT methods is that the links are not always reliable or constant, and the receiver side does not always behave like an ideal current or voltage source. As a result, in order to have a reliable source when a WPT method is in place, standard implantable electrical neurostimulators usually have a small energy storage unit [11]. If the local power storage unit is minimized or removed altogether, the control of the charge cannot be made by setting the duration of the stimulation pulse. As a solution, and to ensure activation efficacy, we propose to introduce charge metering techniques in the neurostimulator design.

III. POWER EFFICIENT TECHNIQUES

The use of a constant current source is common in traditional stimulation schemes, but it wastes a lot of power because the supply voltage is commonly designed for the worst case when the load impedance and thus the voltage across the ETI are high [5]. There are many techniques those can be implemented to improve the power efficiency of implantable electrical neurostimulators. One popular method is the implementation of a current source with an adaptive power supply [12], but it still wastes quite some power in multichannel operation. This is because its adapted voltage compliance would still cause power losses in those channels with smaller load impedances [5].

The ultra-high frequency (UHF) pulsed stimulation approach is another promising power-efficient technique. The UHF approach takes advantage of the capacitive behavior of the cell membrane to integrate a series of high-frequency (in the order of MHz) pulses and build up the charge required for cell activation [13]. The UHF pulses can be delivered to multiple channels in an alternating fashion, significantly improving the power efficiency in a multichannel configuration [5].

If the implant is being powered from a battery, the UHF technique can be applied by using a DC-DC converter to generate UHF pulses [5]. On the other hand, if the implant is being powered from a wireless power transfer link, the signal can be "directly" used for the UHF technique by means of a simple full-wave rectification [14]. This eliminates AC/DC converters and other power management blocks from the power path between the WPT link and the tissue, thereby increasing the power efficiency of the system. Both batteries and WPT methods can be used for LF stimulation and for KHFAC blocking schemes, increasing their power efficiency.

IV. SAFETY CONTROL TECHNIQUES

The proposed neurostimulators must comply with safety standards for medical applications. To ensure stimulation safety, it is crucial to have a charge-balancing technique in the system that can monitor and compensate the charge accumulation on the ETI. This ensures that the voltage across the ETI remains within the safety limits.

A. Charge Balancing Techniques for Low Frequency Stimulation

For LF stimulation, CB is usually implemented by a blocking capacitor or high-pass filter in series with the stimulation current source, to eliminate the DC component of the source. This technique cannot ensure safety because of the serious nonlinearity of the ETI [10]. Besides, the blocking capacitors are usually in the order of μF, which are not practical for integrated stimulator designs, especially for multichannel operation.

Other common CB practices match the charge in the cathodic and anodic phases [15]. This method does not account for the nonlinearities of the ETI and, as a result, also cannot guarantee safety [6].

A third technique is passive discharging during the interpulse delay in every stimulation cycle [16]. For this, the electrodes are grounded after each bi-phasic (cathodic and anodic) pulse. However, this method lacks accuracy because of the uncertainty about the residual charge after each stimulation phase. In addition, the interpulse delay might not

be long enough to fully discharge the electrodes due to the large time constants of the system.

Pulse insertion is another popular technique [17]. As the name suggests, it takes advantage of the interpulse delay to inject some extra pulses into the tissue and compensate for the residual positive or negative charge at the ETI. However, the compensation pulse may evoke unwanted action potentials.

Due to the above reasons, active CB techniques are becoming more and more important as they can automatically monitor and control residual charge on the electrodes. Active CB senses the offset voltage and then compares it with the reference voltage. This control error is used in a negative-feedback loop to automatically adjust the cathodic and anodic charge. The control offset voltage is usually chosen as 0 V. In order to balance the charge, the negative-feedback loop can control either the amplitude [17] or the duration of the cathodic and anodic phases [18].

The above-mentioned techniques do not prevent unsafe charge accumulation, but instead they compensate for it *a posteriori*. Here, a new design is proposed, which actively measures the voltage across the electrodes during stimulation. The second phase of the biphasic stimulation pulse stops when said voltage is within the safety window. The innovation of the proposed approach is that it is preventive as opposed to compensative. Also, it is reasonable to assume that this new method consumes less power per pulse.

In the proposed system, depicted in Fig. 1, the efficacy of stimulation is ensured by matching the amount of charge between subsequent stimulation pulses. In order to do so, a charge-metering circuit similar to the one presented in [19] is proposed. In this case, the circuit is not used to match the charge between the two phases of the biphasic stimulation pulse, but, instead, it is used to match the charge between the activation phases of subsequent biphasic pulses.
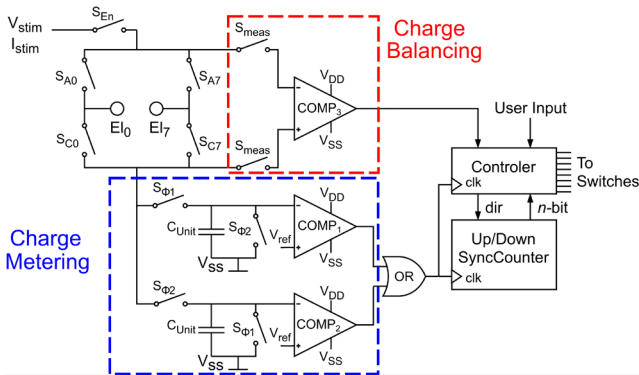

Fig. 1. Architecture of the charge-metering system (blue) in combination with the charge-balancing system (red).

As explained in [18], the charge-metering circuitry consists of two parallel branches. Each branch uses a unit capacitor C_{Unit} to measure the charge being delivered to the tissue. Every time said capacitor is charged to V_{ref}, the comparator connected to it generates a trigger signal that switches the $S_{\varphi 1}$ and $S_{\varphi 2}$ switches, thus charging C_{Unit} in the second parallel branch, while discharging C_{Unit} of the first branch. The amount of charge associated with each

trigger signal is defined by $C_{Unit} \times V_{ref}$. Thus, the total delivered charge can be monitored using a simple digital counter. The main advantage of a double charge-metering branch is that C_{Unit} can be in the order of picofarads, which makes the system suitable for full integration. A detailed timing diagram of the operation of the charge metering and CB is presented in Fig. 2.
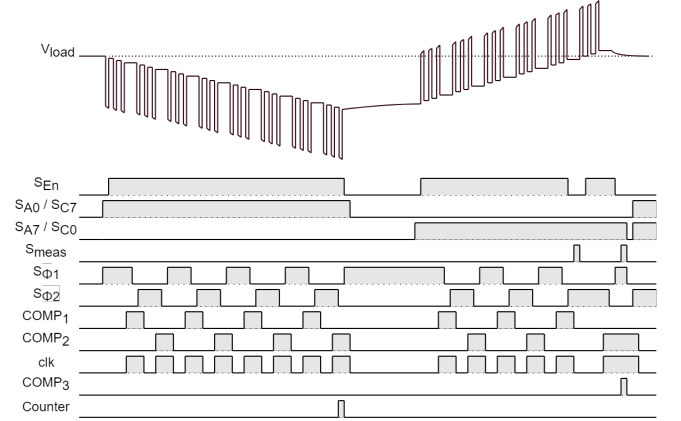

Fig. 2. Timing diagram of the proposed system. In this example, the counter is set to 8 counts to illustrate the concept more easily.

The direct measurement of the voltage for CB is possible due to the architecture of the charge metering circuitry that is already present for efficacy. Every time a comparator is triggered, after C_{Unit} has been fully charged to V_{ref}, the stimulation is interrupted and the voltage across the electrodes is measured closing the S_{Meas} switches. If the voltage difference is far from the safety window, the stimulation is continued. Otherwise, the second phase is terminated and the stimulation pulse ends. Because the application allows for large interpulse delays, the electrodes can be shortened after each pulse, to decrease the residual voltage even further.

B. Charge Balancing Techniques for Kilohertz Frequency Alternating Current Stimulation

For safety control of KHFAC stimulation, the interpulse delay is often too short, hence most of the safety techniques mentioned above, except from the active CB, cannot be applied because there is no time for charge compensation. For a KHFAC stimulator, we propose the use of a pulse-width modulator (PWM) in a negative-feedback loop as an active CB technique [20]. The block diagram of the stimulation system with active CB is as in Fig. 3. The filter-less boost DC-DC converter and the H-bridge are used to generate biphasic stimulation currents. D1 is defined as the duty cycle of the boost converter clock signal. From the working principle of the boost converter, different stimulation intensities can be gotten by adjusting D1. In order to do charge balancing, the electrode offset voltage is automatically controlled by continuously adjusting the duty cycle of the H-bridge clock signal. The offset voltage, V_{os}, across the load is measured by subtracting the DC components of the voltages at both stimulation electrodes, by means of two 1st-order passive RC filters with a cut-off frequency of 1 Hz and a difference amplifier. The safety reference voltage, V_{ref}, is set to 0 V in this work. The proportional controller, A, is needed to ensure stability and

accuracy of the negative-feedback loop. Finally, the amplified control error, V_{err}, is used to adjust the duty cycle the H-bridge, through a voltage-controlled pulse width modulator (PWM).
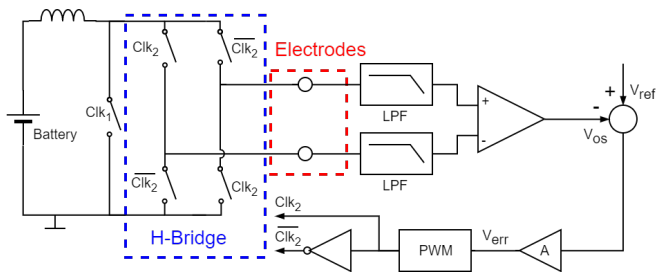

Fig. 3. System overview of the stimulation system with active CB.

To validate the safety control scheme, The complete system was implemented on a printed circuit board (PCB). the proposed system was used to drive a titanium electrode array in a phosphate-buffered saline (PBS) solution. The offset voltage on the electrodes was measured with a multimeter (Hewlett Packard 34401A) for different stimulation intensities that were set using the duty cycle of boost converter clock (D1). First, the active CB control system was disabled. The resulting offset-voltage measurement results are shown in Fig. 4. The offset voltage went up to 1.3 V when D1 increased to 95%, as a result of the nonlinearity of the ETI and charge mismatch between the cathodic and anodic phase. It means that charge balancing is necessary for safety of the stimulator. With the active CB working, the offset voltage successfully stays within the safety window of ±50 mV for all different stimulation intensities.
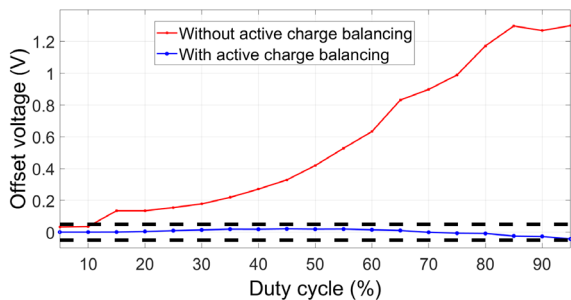

Fig. 4. Measured electrode offset voltage as a function of stimulation intensity. The dashed lines indicate the safety window of ±50 mV.

V. CONCLUSIONS

This paper discusses circuit design considerations for implantable electrical neurostimulators, including the energy source, power-efficient design and safety-control techniques. The UHF technique is used for improving power efficiency in the circuits, regardless of the nature of the power source or the stimulation requirements. Active charge balancing (CB) loops are adopted to ensure the safety of the stimulator, either by actively measuring the voltage across the electrodes during stimulation for low-frequency stimulation applications, or by controlling the duty cycle of the H-bridge switching for KHFAC stimulation applications.

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