Architecture and Low Power Management of a Deep-tissue Medical Implant System Powered by Human Body Energy Harvesting

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Abstract: Active mechatronic implants applied to provide therapy of insufficient bodily functions and acquisition of biomedical data are an emerging field in the context of Medicine 4.0. Wireless data transmission between the implant and out-body devices enables patients and health care professionals to access physiological data as well as take technical control and also allows for home monitoring solutions. Due to the limitations associated with primary batteries or conventional wireless power transferring methods in deep-tissue layers, human body energy harvesting is a promising alternative or complement for power supply. A high efficient power management in order to reduce the implanted device's energy consumption is not only requested to effectively use the limited amounts of energy harvested but also contributes to extend implantation times and thus avoid invasive surgical procedures. This paper presents solution approaches for both software- and hardware-based low power management and storage options for active deep-tissue implants using hybrid energy storage systems and considering miniaturisation requirements of devices powered by energy harvesting.

1 INTRODUCTION

While battery-powered medical implant devices such as pacemakers, neurostimulators or cochlear implants are commonly applied and widely accepted, the trend towards energy harvesting from the human body not only opens a completely new field of novel energy self-sufficient implants with new actuator principles, but also addresses the disadvantages associated with primary battery technologies, such as dominating the device's size as well as the frequent need for replacement or recharging. Devices powered by harvested energy have a longer lifetime and are considered to provide more comfort and safety than battery-powered implants (Hannan et al., 2014).

Conventional approaches for the energy supply of implantable medical devices (IMDs) such as transferring energy from outside the body using wires or inductive coupling are associated with several limitations, especially regarding size, bio-compatibility and the implantation depth power can be transferred into. Particularly the powering of deep-tissue devices with implantation depths >10 cm presents a challenge, making body energy harvesting an interesting alternative or complement.

According to Paulo J. & Gaspar P.D. (2010) the produced power of the human body ranges between 81 W during sleep and 1630 W while sprint walking. As this is potentially sufficient energy to power microelectronic devices, several approaches to harvest energy from the human body have been proposed. However, the usable amount of harvested energy to power medical devices underlies several limitations, requesting a low power architecture design as well as an efficient power management. The required miniaturisation of the harvesting device and low efficiency factors restrict the total amount of energy that can be harvested. Dependent on the harvesting principle, the used energy source may not

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be permanently available. Furthermore, the human body presents a perfectly balanced energy system – the consequences of a sudden energy removal from its inner workings have not been well studied so far.

The design of active deep-tissue IMDs presents numerous challenges, not only concerning their energy supply but also regarding a secure wireless communication between the implant situated in deep-tissue body layers and an out-body device. Conventional communication principles have various limitations, especially regarding their size and transmission range in human body tissue.

This paper features specific challenges regarding the system architecture of active deep-tissue IMDs powered by human body energy harvesting. A possible architecture of a system powering a radio module for wireless communication and an actuator or sensor unit as well as intended low power management options are presented. In order to optimise the energy storage efficiency, the combination of two different storage technologies seems suitable since characteristic disadvantages of one technology can be absorbed by the other (Böhm et al., 2018). Thus hybrid systems combining the advantages of lithium-ion batteries (LIB) and ultracapacitors (UC) are used in the presented system.

2 HUMAN BODY ENERGY HARVESTING PRINCIPLES

Mateu et al. (2014) classify two ways to harvest energy from the human body: active and passive power. Accordingly, passive power is harvested from the patient’s or user’s everyday actions, such as breathing or walking motions, whereas active power is harvested from actions the person especially executes for harvesting reasons. This paper focuses on the former harvesting form only.

Regarding the underlying physical principle, harvesting methods can be divided into three types according to Figure 1.

2.1 Mechanical Energy

Various approaches to harvest mechanical energy from human body motions or body fluidic flows have been presented in literature. As an example, mechanical energy can be harvested through piezoelectric elements in various in- and out-body positions. Approaches to drive piezoelectric elements by the rotation of joints (Cheng et al., 2015; Hannan et al., 2014), the vibrations of human breathing motions (Saida et al., 2018), the pulsating energy of the aorta (Zhang et al., 2015) or the pressure generated in shoe soles by human walking motions (Hannan et al., 2014; Johari & Rashid, 2017) have been shown. Furthermore, concepts to power harvesters by running turbine generators are proposed. Micromechanical turbines can be driven by footstep-induced airflow (Fu et al., 2015) or the cardiac output blood flow in a peripheral artery (Pfenniger et al., 2014). Niroomand & Foroughi (2016) designed a rotary magnetic generator to harvest energy from walking motions.

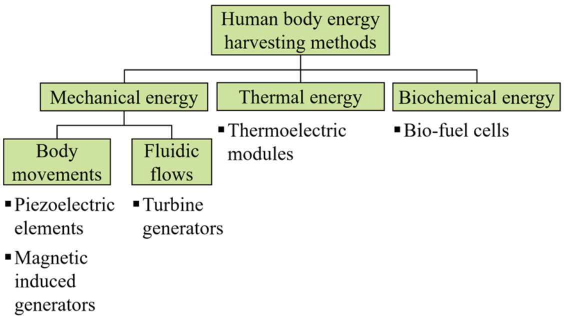

Figure 1: Human body energy harvesting methods and examples.

2.2 Thermal Energy

Thermal energy can be harvested from temperature differences due to the Seebeck Effect, making this principle an option to harvest energy from human body heat differences. As shown in several publications presenting thermoelectric modules, usually comparatively low output powers in the range of µW are generated as the associated temperature gradients typically do not exceed a few K. In the early work of Strasser et al. (2003) a CMOS thermoelectric generator harvesting electrical energy from waste heat is presented, achieving a power output of 1 µW with generators in the size of 1 cm² and a temperature gradient of 5 K making this sufficient to power a human wrist watch by body heat. In (Wang Z. et al., 2009) a thermoelectric generator creating an output power of 0,3 nW when worn on the human body is presented. Shi et al. (2018) conduct wrist wearing experiments with a copper-foam-based wearable thermoelectric generator to power a miniaturised accelerometer.

2.3 Biochemical Energy

Bio-fuel cells are an alternative approach to power IMDs by using bodily fluids surrounding the implant as a potential energy source. Hereby biochemical energy is transformed into electrical energy based on electrochemical reactions processing glucose or oxygen (Ben Amar et al., 2015). Different approaches to harvest energy using body fluids such as urine, saliva (Göbel et al., 2016) or human perspiration (Jia et al., 2013) have been proposed.

3 SPECIFIC CHALLENGES REGARDING DEEP-TISSUE IMPLANTS

The development towards in-body systems that are in a more miniaturised scale enables implanting surgery procedures to be less invasive and makes the implant less impairing for the patient. According to Cadei et al. (2014) the size limit typically is in the range of 1 cm³. Active medical implants in deep-tissue body layers present specific challenges regarding their design and functionality in comparison to established implants closer to the body surface, such as cardiac pacemakers or neurostimulators. Since wires implanted in the human body present a potential infection risk, wireless communication and energy supply is desired.

3.1 Communication

In order to enable patients and health care professionals to access physiological data or take technical control, e.g. to activate the system's actuators, a secure communication path between the implant and a corresponding out-body device needs to be established, using the human body tissue as a transmission medium.

Teshome et al. (2019) present a comparison of different wireless communication principles regarding their transmission range. Accordingly, antenna based radiofrequency (RF) signal communication enables by far the widest in-body transmission range of up to 2 m, while electric-field based and ultrasonic communication enable much smaller ranges of up to 10 cm. Other presented technologies are too limited in the transmission range to be taken into consideration for communication with deep-tissue implants.

The transmission of tissue with RF signals has been investigated in various works. Living body tissue generally absorbs RF signals and is an inapplicable channel to high-frequency electromagnetic waves. (Teshome et al., 2019) Short- wave signals, such as the in wireless body area networks (WBAN) widely used 2,36 – 2,4 GHz band appear to be not suitable to communicate with deep-tissue implants as attenuation values increase with frequency (Alomainy et al., 2006). Therefore, longer-wave electromagnetic signals such as the 400 MHz frequency band set aside in the Medical Implant Communication Service (MICS) specification especially for medical implants and devices are proposed. Since the size of the RF-enabling antenna is proportional to the wave length of the used signal, shorter frequency signals, however, have the downside of requiring larger antennas potentially using more space of the implanted unit.

3.2 Energy Supply

Active implants not only feature a communication unit but also a logic unit providing adequate computing power as well as an actuator or sensor module, all of which require a sufficient wireless energy supply.

Inductive coupling is a commonly used principle enabling mutual inductance between a primary coil integrated in an out-body station and a secondary coil implanted in the human body. This method is limited to short implantation depths as with transcutaneous IMDs or implants closer to the body surface since the power absorbed by human tissue has to be minimised in order to prevent tissue heating or other side effects. The size of the coils usually is in the range of several cm as the coupled energy is dependent on the coil size, which counteracts the requirement of a high miniaturisation (Ben Amar et al., 2015).

Regarding the limitations associated with conventional methods, energy harvesting is a promising alternative to power deep-tissue medical implants, provided that the required energy to power the device is harvested in the body region the implant is situated in.

To efficiently generate electrical energy from thermal harvesting, there needs to be a sufficient temperature difference between the hot and cold end of the applied thermocouple since the output power depends on the dimension of this temperature gradient (Ben Amar et al., 2015; Cadei et al., 2014). Between the human body and the environment there is only a small gradient in the range of 3 – 5°C (Mateu et al., 2014), but in deep-tissue layers body temperature differences are even smaller making them too insignificant to effectively harvest thermal energy, thus only the harvesting of mechanical energy is taken into consideration by the authors.

4 SYSTEM STRUCTURE AND OPERATION

Due to the characteristics of human body energy harvesting regarding the time periods power is

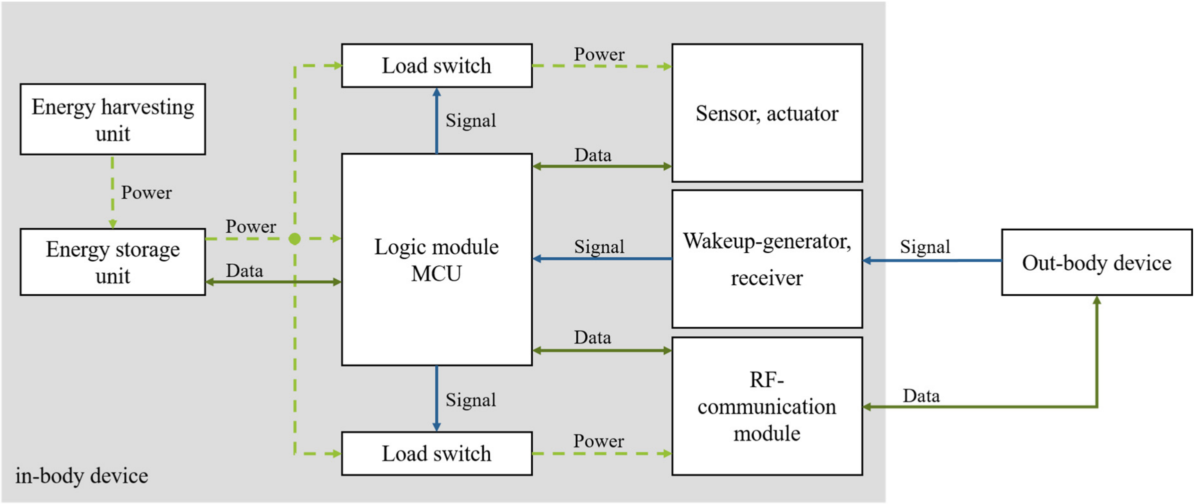

Figure 2: Architecture of the proposed system showing data, signal and power flow of the in-body and out-body device.

generated and the therefore required efficient power management as well as the presented challenges of communicating with devices situated in deep tissue, suitable system architectures are required addressing these issues.

The aim of the presented concept is to set up a general system which can be applied for various technical principles of energy harvesting, enable an efficient power management of the limited amounts of harvested energy and provide a communication unit in order to establish a communication path between the IMD and an out-body device when requested by the patient or operator. Since the energy source may only be temporarily available, the architecture is designed to provide flexibility regarding irregular time periods of the energy harvesting process and the therefore strongly varying load peaks.

As presented in Figure 2, the proposed system consists of an energy harvesting unit, an accumulator unit for energy storing and a logical unit regulating the subsequent sensor or actuator and RF-communication module. In order to reduce the system's energy consumption, load switches regulated by the MCU are applied to turn on and turn off the powering of the sensor or actuator and communication unit. A wakeup-receiver is provided to receive signals from an out-body device to wake up the MCU from a power saving mode when system operation is required by the patient or health care professional. In the following the intended energy storing unit and power management methods are described in detail.

4.1 Energy Storage Unit

The accumulator unit of the circuit fulfils two essential tasks: The storage of the electrical energy generated by the harvesting module and the subsequent supply of the required energy for the logic module and actuator or sensor unit. The type of the energy storage unit depends on the amount of energy to be stored, the required power drain, the storage duration and the target number of charge cycles.

The most commonly used type of energy storage in IMDs are lithium ion batteries (LIB). They are characterized by a high energy density and low self-discharge which enables a long storage duration. Since LIBs are solid state batteries, the mobility of the charge carriers within the batteries is limited. This also results in a limitation of the available power density. Another disadvantage is the limited number of charge cycles (Yu et al., 2018). Furthermore, the degradation of the LIB capacity will be accelerated when there are power peaks during the charging (Zou et al., 2015).

As stated before, this approach also considers energy generating methods harvesting from body motions that are only temporarily executed by the patient. In these cases, lithium-ion batteries are not suitable as due to their low power density they cannot absorb all energy provided and can even be damaged by occuring power peaks (Zou et al., 2015). A potential alternative to LIBs are ultracapacitors (UC). Due to their very high power density compared to LIBs, UCs can absorb almost the entire energy generated during a short-term power peak (Burke, 2000). The better power drain compared to the solid state LIB is based on a higher mobility of the charge carriers. However, since the free movement of the charge carriers results in a higher self-discharge, the absorbed energy's storing duration in the UC is comparatively short. In the presented circuit concept, the storage duration is desired to be as long as possible, so using a UC alone is no ideal alternative to a LIB.

One possibility to achieve all necessary requirements for the energy storing unit is the use of a hybrid energy storage system (HESS). A HESS combines a classic LIB with a UC. The UC takes over the short-term absorption of high power amounts and protects the battery, while the latter can store the energy for a longer period of time so that it can be used later to power the downstream modules. HESSs are already being used in electric vehicles with larger scaling. For example, they make it possible to utilize the short-term high power generated during regenerative braking recuperation with a high degree of efficiency and at the same time protect the expensive lithium batteries in the car from peak power. (Hochgraf et al., 2014; Hu et al., 2018)

There are two possible options for the realisation of a HESS within the framework of the presented circuit concept. In a simpler design, the HESS consists of only one LIB and a parallel-connected UC. This enables an implementation which is easy to realise and allows for a high degree of miniaturisation. (Lukic et al., 2007) Due to a lack of interconnected control electronics, however, the energy stored in the UC cannot be completely utilised for power supply of the downstream units. (Gao et al., 2005) Figure 3 shows a schematic of the second option. A unidirectional DC/DC converter is interconnected between the UC and a LIB. This enables a higher degree of utilization of the energy stored in the UC, but results in a larger space requirement of the HESS, which must be taken into account when designing and using the circuit. (Lhomme et al., 2005)

The energy generated in the harvesting module is temporarily stored in the UC and transferred to the lithium battery via the DC/DC converter. From there, the remaining circuit including the actuator module is supplied with the previously generated energy. Combined with a UC, the LIB is exposed to less stress in terms of varying load peaks during the loading process. As a result, the lifecycle of the LIB is significantly prolonged which enables longer implantation times in the body and thus leads to a minimisation of invasive surgical interventions. (Cao & Emadi, 2012)

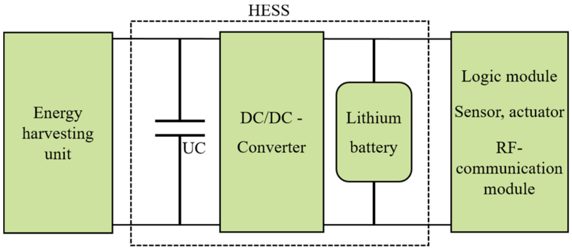

Figure 3: Hybrid energy storage system with integrated DC/DC-converter.

4.2 Power Management Methods

Since the amounts of output power are limited due to the stated reasons, an efficient management of the harvested energy is required to be able to unfailingly power the logic module and actuator or sensor unit according to the patient's needs.

4.2.1 Hardware-enabled Management

Providing that the patient only temporarily communicates with the IMD in order to operate the actuator or access biological data stored, it is determined which of the intended system's modules need to be operated only temporarily. As it is desired to reduce leakage currents caused by passive components, the sensor or actuator and communication modules are only to be powered when their operation is required. This is ensured by an appropriate design of the hardware architecture as presented in Figure 2. Load switches are applied as a basic solution to turn on and turn off the powering of the downstream modules, i.e. the sensor or actuator as well as the RF-communication module.

4.2.2 MCU Wake-up Options

For many applications MCUs are designed in such a way that they are able to enter different low-power or sleep modes in order to reduce their energy consumption. In these modes typically the functionality of different components, such as the CPU, memory or peripheral components, is reduced at different levels or completely turned off.

In order to establish a communication path between the out-body device and the RF-communication module, the system is listening for occurring external connecting requests (Figure 4). In order to reduce the energy consumption, the MCU can be set to turn into a low-power mode between these high-energy consuming listening events. This software-controlling of frequent listening events, however, is connected to the downside that the CPU cannot be turned off which causes an increased energy consumption even in low-power mode, as shown in Figure 5.

In deep-sleep mode, however, the CPU is disabled from executing commands. In order to return to active mode in this case an interrupt needs to be set to be triggered by an external energy pulse received by the wakeup receiver (Figure 4). While this option is the most power-saving as the system is only woken up from sleep-mode when requested by the patient via the out-body device (Figure 5), it presents the challenge of wirelessly transmitting the interrupt impulse through human body tissue. To solve this issue, alternative concepts of power transfer in deep-tissue layers, such as ultrasound wakeup, have to be taken into consideration.

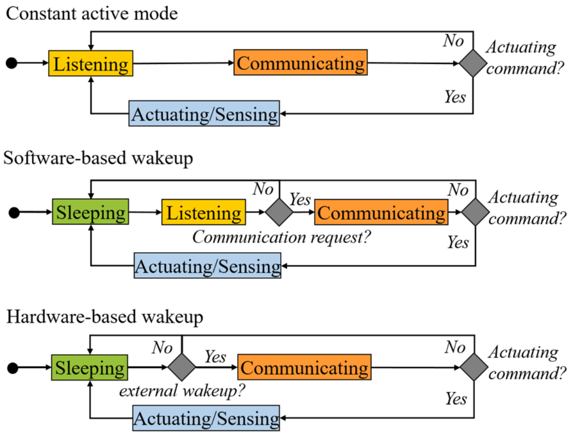

Figure 4: Hardware- and software-based wakeup operation compared to constant active mode.

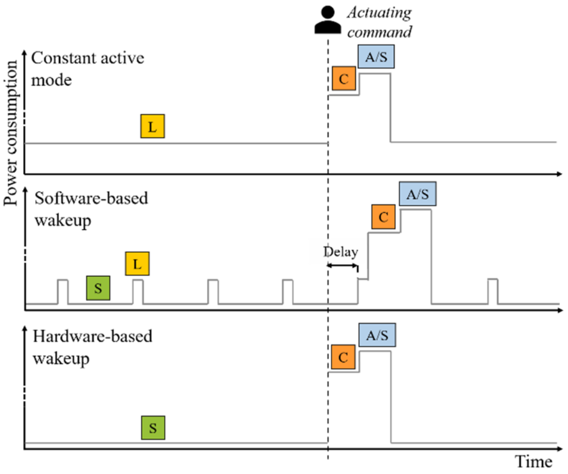

Figure 5: Power consumption levels of hardware- and software-based wakeup operation compared to constant active mode. (S) Sleeping, (L) Listening, (C) Communicating, (A/S) Actuating/Sensing.

5 CONCLUSIONS

Since external approaches to wirelessly power IMDs situated in deep-tissue layers underlay several limitations, human body energy harvesting is a promising powering approach. In this paper therefore a system architecture for an IMD powered by harvesting of mechanical energy is proposed. The presented system provides great flexibility regarding the used harvesting principle and enables the patient to wirelessly communicate with the IMD according to his needs. Since the harvested energy may not be permanently available, hybrid storage systems combining the advantages of conventional LIB and UC are intended to be used for energy storage. Research approaches have shown that these systems not only are able to efficiently process load peaks, but also offer great potential regarding the miniaturisation of the system and prolonged implantation times due to an extended number of possible load cycles. Furthermore, suitable power management options to be able to power an RF-communication module for data exchange or technical control by the patient as well as an actuator or sensor unit are proposed. As a result, the energy consumption of the IMD potentially can be considerably reduced.

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