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Design, Simulation and Analysis of a Replacement-free ImplantedThermoelectric Generator based Pacemaker

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Abstract— This paper deals with a novel design approach to pacemakers that will enable the implanted pacemakers to be replacement free. The major drawback of the current design of pacemakers is their expiry date of around twelve years. This timeframe is intensified by the lowered age range when heart disease turns critical. Pacemaker failure is one of the most common forms of heart disease, and implanting an artificial pacemaker is the most acceptable and viable solution.

Keywords-Thermoelectric generator, Cardiac pacemaker, buck-boost converter, Heart diseases, Cardiac implantable electronic devices.

I. INTRODUCTION

Pacemakers are medical devices that support the electrical system of the heart. They stabilize abnormal heart rhythms caused by certain arrhythmias and prevent problems that can disrupt or endanger life, such as heart blocks and heart failure. One of the major characteristics of modern cardiovascular implantable electronic devices (CIED) is their longevity [1-3]. Due to the adoption of more complicated diagnostic and therapeutic activities, device complexity has significantly increased over the past few decades. Although the therapeutic advantages of these functions have been thoroughly assessed, the associated energy requirement has not been thoroughly examined [4-6]. The action of the pacemaker itself is simple, as it provides a steady triggering pulse or a synchronous triggering pulse to the heart. The two types of pace makers are synchronous pace makers, and asynchronous pacemakers. The synchronous pacemakers provide a steady triggering pulse to the heart at a fixed rate. The heart will keep beating at this steady rate, which is prefixed when installing the pace maker. In asynchronous pacemakers, the pacing is provided in sync with the existing pace or when needed. The heart problems arising from defect of the body's internal pacemaker, are treatable and the working of the heart can be restored to almost normal functioning. So pacemakers and the design, development, and testing of pacemakers form an important part of medical research.

CIEDs are in by themselves, very simple electronic systems, and can be implemented easily. The fact that they have to be implemented internally through an intrusive operation, means that there have to be extensive safety measures, and safety testing is necessary before the devices are approved for human trials [7]. This makes pacemaker research and development a very expensive area. Hence, pacemakers have hardly undergone any major transformations since their inception. The current practically used pacemakers are mostly the same design implemented with safer, better, and smaller form factor components [8, 9]. Most of these improved designs concentrate on extending the life of the pacemaker ignorer to avoid the inevitable surgery that is necessary when the pacemaker has to be replaced. In the current scenario, the replacement time frame is about 10-12 years, with an ideal case situation providing about 15 years of life [10]. The need for replacement surgery is the major drawback of getting an artificial pacemaker implanted. This not only incurs an unnecessary medical cost, for the procedure itself, but it also causes severe setbacks in terms of earning capacity, missed days at work, recuperation times, reduced productivity, and most importantly a significant loss in the quality of life [11-13]. Pacemaker replacement for battery depletion is generally technically less challenging than new implantation but is associated with complications that may place the patient at substantial risk, including system infection requiring complete extraction. This is one of the main reasons for the development of a replacement-free pacemaker. The current research is trying to avoid or extend the life of the pacemaker. This is mainly done by making the battery rechargeable, and implementing some sort of a remote charging system, like electromagnetic waves, induction, or even piezoelectric effect [14]. Most of the

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technology is still in the search, testing, or development phase, and the medical industry as a whole is reluctant to adopt these new technologies as they only provide a short-term solution. The surgery for replacing the pacemaker also carries with it a risk of infections, which puts an additional toll on the patient's body. The replacement free CIED also eliminates this infection risk, leading to saved recovery time, and the efforts by the patient's already weakened body, to recover from infections. It also eliminates the risk of lead damage with each CIED replacement due to battery depletion and the need for additional antibiotics that will put a strain on the liver. Limiting generator replacement also reduces the risk of damaging the leads during the procedure.

This work proposes a novel implantable pacemaker design that avoids the need for replacement surgery. The work, details the concept, design, and development of such a pacemaker implementation, at a simulation level. The proposed pacemaker utilizes the advancements in rechargeable batteries and builds upon the research already done on the non-contact charging of implantable pacemakers. The rechargeable battery technology for implantable pacemakers is already researched and established by several research works. The proposed work combines this rechargeable technology, an implantable TEG, and an implantable pacemaker, to create a novel design for a replacement free implantable pacemaker, that is proposed to last the patient's lifetime. The replacement-free pacemaker will make the experience of living with a pacemaker a less traumatic one and will improve with quality of life of the patients tremendously. This will also lead to cost savings for the economy and the individual, by eliminating the need for a battery replacement surgery and eliminating the trauma to the body by replacing a pacemaker that was implanted for 12 years.

II. MATERIALS AND METHODS

A thermoelectric generator is a transducer that can generate electrical energy from temperature variations. This TEG can act as a source of power that can generate pulses, with enough energy for a pacemaker, from the variations in human body temperature. This power will be affected by environmental conditions, and hence the delivered power may not be stable. To overcome this, a DC converter is implemented to solve the variations in environmental conditions that affect the stability of the power generated by TEG. The method that we propose in this work is using the dc to dc converter, implemented in the form of buck-boost converter and it is used to stabilize the power output

A. TEG Design and details

In the proposed design for a novel, replacement-free cardiac pacemaker, a power source based on TEG is used to power the pacemaker. A TEG can absorb both cold and heat energy variations that occur naturally in the body, and provide an electrical output [15]. A thermoelectric module is the main part of a TEG. This includes a heat source, cold source, and thermal power sections in between. The Seebeck effect is used by thermoelectric generator semiconductors to produce voltage. The principle of thermoelectric generation is shown in figure 1.

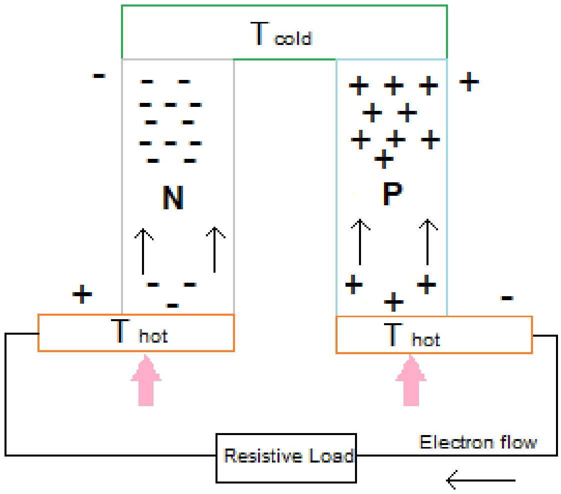

Figure 1: Principle of thermoelectric generation

[T- temperature, N- N-type material, P- P-type material]

The thermoelectric units incorporate three components: the solder layers, second is the n-type and p-type semiconductors and the third being the electric conducting plates. The heat and cold sources are used in the thermoelectric unit, at the respective ends of the loops for the current generation. To achieve effective thermoelectric conversion, semiconductors with a high ZT value are chosen for the implementation. The thermoelectric materials figure of merit, ZT is a well-defined metric to evaluate thermoelectric materials. It can be calculated from equation 1.

$$ZT = \frac{S^2 T}{\rho k} \quad (1)$$

where S is the Seebeck coefficient
T is the absolute temperature
ρ is the electrical resistivity, and
k is the thermal conductivity

One thermoelectric device is connected using conducting plates made of copper, with columns of n/p type of thermoelectric pairs. This is also made from high purity alumina ceramics in order to maximize efficiency. The components of the thermoelectric generator are bonded together, the low electric loss solder material [16]. The equations that determine energy conservation and charge continuity are given below.

$$\rho C_P \frac{\partial t}{\partial T} + \nabla . \vec{Q} = Q \quad (2)$$

$$\nabla . \left(\vec{j} + \frac{\partial \vec{d}}{\partial T} \right) = 0 \quad (3)$$

In the equation,

$\rho$is the density, $\vec{Q}$ is the heat flux,Qis the volumetric heat,

C_P is the specific heat at consonant pressure, and $\vec{j}$ is the electric current intensity. The heat flux and electric current intensity are calculated as,

$$\vec{Q} = P. \vec{j} - S. \nabla t \quad (4)$$

$$\vec{j} = \mu . \left(\vec{IE} - \mu . \nabla t \right) \quad (5)$$

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P is the Peltier coefficient.
$P = \nabla t$. describes the relationship between the Peltier coefficient and the Seebeck coefficient.
The dielectric equations are used to compute dielectric flux density,

$$\vec{d} = \varepsilon.\vec{IE} \qquad (6)$$

$\vec{IE}$ is the electric field intensity and
ε can be referred as the dielectric coefficient.

As mentioned above, the electric field intensity is not constant, and the electromagnetic field does not change with time. This can be obtained as the gradient of electric energy φ.

$$\vec{IE} = -\nabla\varphi \qquad (7)$$

The steady-state condition can be used to derive the thermoelectric coupling formulation, as shown in the equations below

$$\nabla.\left(P.\vec{j}\right) - \nabla.(S.\nabla t) = \vec{j}.\vec{IE} \qquad (8)$$

$$\nabla.(\delta.\mu.\nabla t) + \nabla.(\delta.\nabla\varphi) = 0 \qquad (9)$$

The heat generated can be measured based on the Joule heat Equation (8). The size of each part can be denoted as $\text{length}(l) \times \text{width}(W) \times \text{height}(h)$. For the implementation, the hot and cold temperatures are provided at a constant level for the thermoelectric unit. The boundary conditions for the surfaces and the sides are assumed. To attain maximum possible efficiency and maximize the power generated by the thermoelectric unit, the voltage load is connected on the two sides. Two of the criterion that is used to evaluate the performance of TEG, are thermoelectric conversion and power output. The power output (o) produced and the conversion efficiency (η) are related directly to the TEG's shapes, materials used to manufacture the TEG, and size of the TEG. The conversion efficiency and power output can be calculated based on thermodynamics theory, based on the equation (10) given below,

$$\eta = \frac{\Delta t.r_l}{t_1(r_1 + r_2) - \frac{\Delta t.r}{2} + \frac{(r + r_l)^2}{2r}} \qquad (10)$$

Where, $\Delta t = t_1 - t_2$,
t_1 is the hot temperature,
t_2 is the cold temperature.
r is the semiconductor internal resistance,
r_l is the load resistance.
To reduce complexity, the Thomson effect is omitted, which refers to the independent temperature μ.
In the condition $\frac{r_l}{r} = \sqrt{(1 + zt)}$, when the maximum value is obtained, that is taken as conversion efficiency. The conversion efficiency can be described as,

$$\eta = \Delta t.\frac{\sqrt{(1 + zt)} - 1}{t_1\sqrt{(1 + zt)} + t_2} \qquad (11)$$

Where, $t = t_1 + t_2$.
At, $r_l = r$ the expression for maximum output power becomes,

$$P^{max} = \mu^2\frac{(t_1 + t_2)^2}{4R} \qquad (12)$$

The thermoelectric unit generates power output from the energy of the heat source, based on the equations described above. The thermoelectric unit is always affected by the variations of the heat or cold energy in the environment. To stabilize and enhance the output produced by the TEG, a DC-DC converter is implemented in this work.

B. Replacement-Free Pacemaker Design

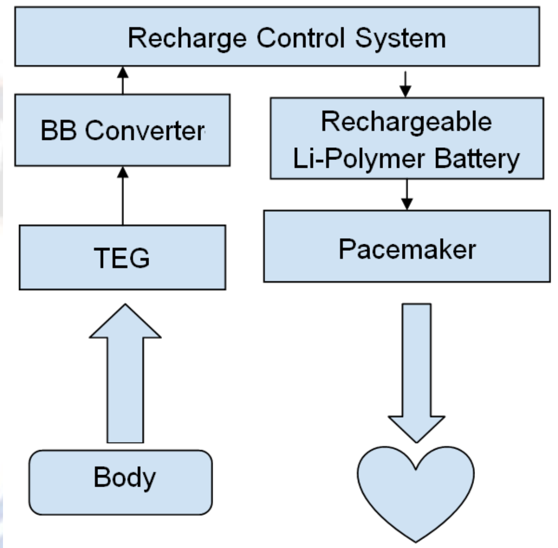

Figure 2: Block diagram of replacement free pacemaker [TEG- thermoelectric generator, BB- Buck-Boost]

Figure 2 depicts the basic block diagram, of the proposed replacement free pacemaker. The basic high-level design is depicted in the block diagram. The diagram shows the modification to the current pacemaker design, that is to be implemented to make the pacemaker a replacement-free one. The TEG system is connected to the body, such that the temperature differences that inherently arise in the body are captured by the TEG and are converted into electrical power. The amount of energy that is generated by the TEG is dependent on several environmental conditions. This power is given to a DC to DC Converter which forms the second block of the pacemaker system. The buck-boost converter, which is the DC-to-DC converter, in this current design, is capable of stepping up or stepping down the voltage. This ensures that steady output power is delivered by the device. This power is passed through a control algorithm and is utilized to charge a rechargeable battery, whenever there are sufficient power levels to charge the battery. The rechargeable battery is used to power the pacemaker as the traditional pacemaker is powered. The pacemaker draws power from the battery, similar to the current design of an implantable pacemaker. This battery is the one that drains itself out in 12 years. The addition of the TEG recharging system enables the battery to last as long as required.

C. Buck-boost converter design

D. TEG Design and details

The replacement free cardiac pacemaker is powered using the

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TEG because it generates electric power based on temperature variations between hot and cold sides. TEG is gaining popularity as a device that can be used for power generation, especially as the power source for the battery-less cardiac pacemaker. In the current implementation, the maximum power generation using a DC-DC converter must be incorporated to bring the operating point of the TEG to its optimum. This is necessary so that the TEG generates the maximum possible power, and at the same time provides a constant voltage to the load. In this work, a buck-boost converter-based design of the DC to DC converter is used, based on our work that is already published [15]. The modeling of the converter is given in the section below.

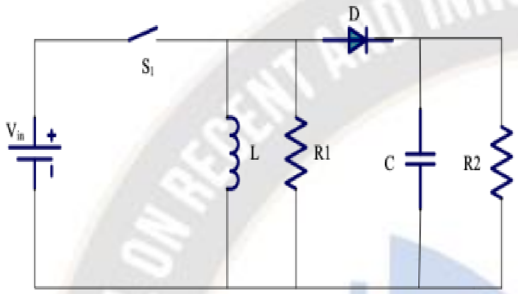

Figure 3: Circuit Diagram: Buck-Boost converter
[D- diode, L-inductor, C-capacitor, R- resistor, S -switch]

The circuit diagram of a buck-boost converter is shown in figure 3. The buck-boost converter can be implemented to either step-down or step-up the output produced by the TEG. The step-down or step-up operation is determined based on the duty ratio, related to the TEG input voltage. The buck-boost converter works based on two modes of operation, namely the boost operation and the buck operation. In the buck mode of operation, the input voltage is higher than the output voltage.
The two modes of operation of the buck-boost converter's mode of operation switch, and will operate concurrently [17]. When the switch is in the ON condition in the converter, an inductor that stores energy as its magnetic field is used for the charging. Similarly, when the switch is in the OFF condition, the inductor discharges and supplies energy to the load. The inductor also limits the current when the load changes suddenly. A capacitor at the output is also used to regulate the voltage.

The buck-boost converter has two modes of operation namely the continuous conduction mode and discontinuous conduction mode. If the current through the inductor L never falls to zero during a commutation cycle, the converter is said to operate in continuous mode.

$$V_{OUT} = \frac{D}{1-D} V_{IN} \qquad (13)$$

Where V_{OUT} is the output voltage$V_{IN}$is the input voltage, and D is the duty cycle. The design for the inductor, of the buck-boost converter, is given by the equation,

$$L = \frac{(1-D)V_{OUT}}{(\Delta I_L)F_{SC}} \qquad (14)$$

Where IL is the inductor current F_{SC} is the minimum switching frequency of the converter.
The capacitor for the buck-boost converter is given by the equation,

$$C = \frac{D}{\{RF_{SC}\}(\frac{\Delta V_{OC}}{V_{OUT}})} \qquad (15)$$

Where ΔV_{OC} is desired output voltage change due to the overshoot, and R is the resistance
Equations given above are used to deliver the maximum power from the thermoelectric generator, using the buck-boost converter design. This ensures the proper continuous functioning of the artificial pacemaker, that the design is used to power.

III. Results and Discussion

The TEG system implemented with the buck-boost converter, when combined with an intelligent recharge control system, can be ideal for a small rechargeable battery. The performance of the proposed design for a replacement-free implantable cardiac pacemaker is presented and verified in this section. The Thermoelectric generator, followed by the buck-boost implementation of a DC-DC converter, a battery recharging system, and the rechargeable battery together forms the initial sections of the replacement-free cardiac pacemaker. The circuit diagram of the DC-DC converter, a common cardiac pacemaker with TEG, is developed and tested in this section. The design is implemented using the Orcad/Pspice platform. The performances of the modules involved are specified below.

TABLE I. IMPLEMENTATION PARAMETERS OF THE PROPOSED METHOD

Descriptions	*Parametes*	*Values*
TEG	Hot temperature	37^{0C}
	Cold temperature	22^{0C}
	Temperature difference	15^{0C}
Buck-Boost converter	Resistor 1	33KΩ
	Resistor 2	10KΩ
	Diode	BYV27-100
	Capacitor	22μF
	Inductor	50μH

The efficiency of power generated, and input voltage supplied to the cardiac pacemaker and its smooth operation, are evaluated based on four modules. TEG is designed and implemented along with a cardiovascular pacemaker, in order to increase the durability of the cardiac pacemaker circuit, by acting as a power source for a rechargeable battery. The two modules are,
Module 1: Cardiac Pacemaker
Module 2: TEG implemented with a Buck-Boost converter

The modules are designed as described in the sections above and their performance is analyzed below. The designed values for the TEG and the buck-boost converter are given in the Table 1.Implantable pacemakers are powered using a high-capacity battery that supplies power to the pacemaker. As discussed before, the life of the pacemaker is determined by the battery life. Once the battery is drained, it has to be

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replaced to ensure the proper working of the pacemaker, and the patient's heart. The circuit diagram for the pacemaker was designed and implemented using Orcad, and this is shown in figure 4.

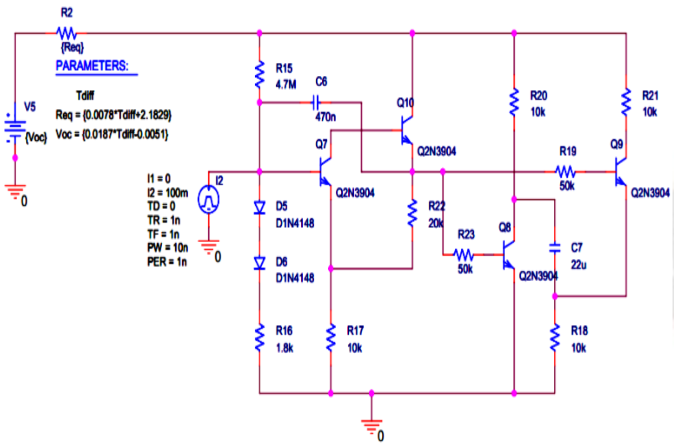

Figure 4: Design of TEG combined with cardiac pacemaker [D- diode, Q-transistor, C-capacitor, R- resistor, I- current, TD- delay time, TR- Rise time,TF- fall time, PW- pulse width, PER- period]

The power source that continuously provides steady 2V output pulses is sufficient for the pacemaker. The general pacemaker is designed in Orcad by reference [18]. Battery-based cardiac pacemaker design parameters are presented in Table 2.

TABLE II. DESIGN PARAMETERS OF GENERAL CARDIAC PACEMAKER

Parametes	*Values*
Resistance (R15)	4.7mΩ
Capacitor (C6)	470nF
Transistor (Q7, Q10, Q8,Q9)	Q2N3904
Diode (D5, D6)	DIN4148
Resistance (R16)	1.8kΩ
Resistance (R17)	10kΩ
Resistance (R22)	20kΩ
Resistance (R23)	50kΩ
Capacitor (C7)	22μF
Resistance (R18)	10kΩ
Resistance (R20)	10kΩ
Resistance (R19)	50kΩ
Resistance (R21)	10kΩ

The hot and cold temperature ranges that the TEG experiences are used to determine the equivalent resistance. This temperature range in which the TEG operates is analyzed and based on this, the voltage output is available to produce the pulses for the pacemaker. The generated input voltage and final output voltage are shown in Figure 5.

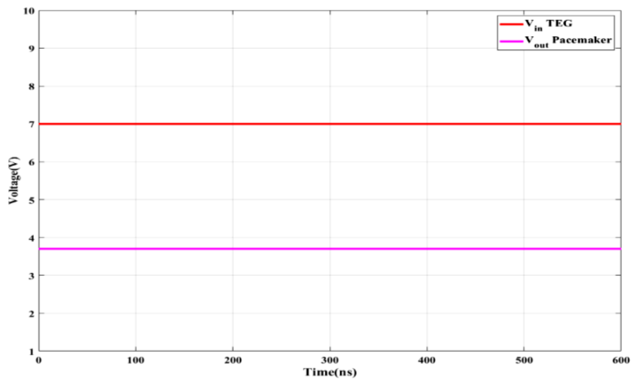

Figure 5: Analysis of TEG input voltage

In certain conditions, the temperature difference may be very low, and that is insufficient temperature difference to provide the required energy to activate the pacemaker circuit. This makes the buck-boost converter very crucial to generate the output required to produce sufficient strength pulses for the pacemaker. Buck-boost converter is carefully designed in such a way as to work with the TEG, to alleviate the high temperature and low-temperature level variations. The buck and boost operations of the design help to maintain a constant voltage level. The circuit design of the buck-boost converter with TEG is presented in Figure 6.

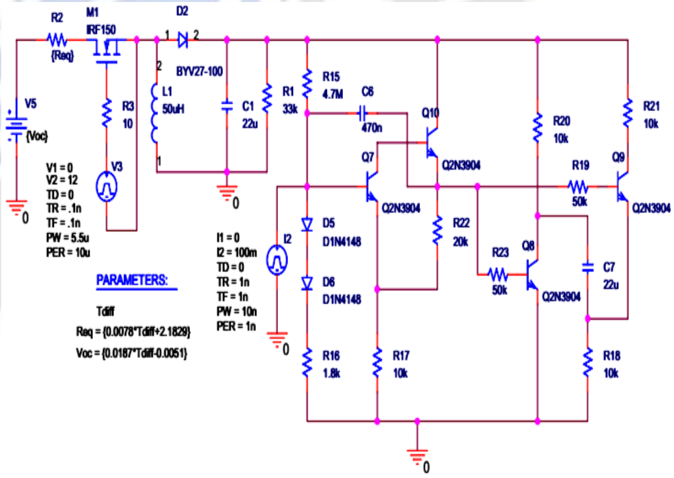

Figure 6: Circuit diagram of buck-boost converter with a cardiac pacemaker

[D- diode, M- MOSFET, Q-transistor, C-capacitor, R- resistor, I- current, TD- delay time, TR- Rise time, TF- fall time, PW- pulse width, PER- period]

The input to the buck-boost converter, that is generated by the TEG is analyzed below. The output voltage of the buck-boost converter is depicted in Figure 7. The figure shows that for operating with the TEG, the buck-boost converter is the most suitable, because this converter offers a stable operation, especially in the varying temperature levels that are present inside the body.

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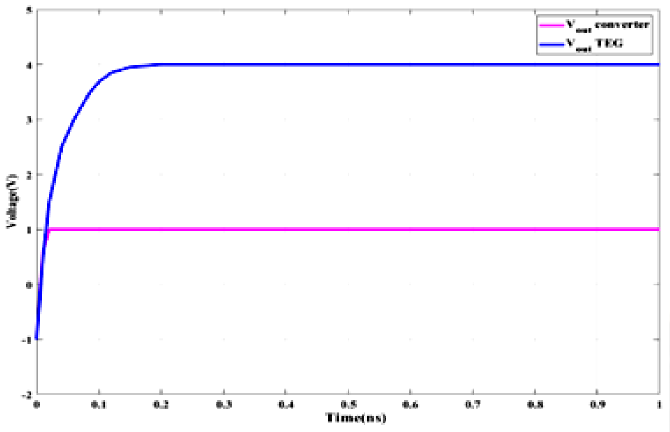

Figure 7: Output Voltage of Buck-Boost Converter

The results presented shows that the proposed system of a replacement-free pacemaker is a very practically implementable solution to the problem of pacemakers having a limited lifetime, and needing replacement after a fixed number of years. The Proposed TEG generation system can provide sufficient current and voltages to recharge the battery at a slow trickle charge system, as proposed by the control system. This slow recharging makes sure the battery does not run out of power and that the recharge cycles are slow and steady so as to keep the level of charge in the battery steady, and sustained over the years [19-21]. Since the Battery itself is designed to last 15 years, the system proposed here will last the lifetime of the patient.

The TEG implementation gives out a minimum voltage of 11.5 V, and a min current of 10mA. The TEG with buck-boost system manages to provide a steady output voltage and current from the TEG system, which has a steady value of 1.5V and 5mA. This steady voltage is used by the Control system to provide a steady trickle charge to the batteries, keeping them charged. This slow steady charging ensures that the battery is ready to handle several years of service.

The rechargeable battery pacemakers were implemented in research settings but were never effective enough to be adopted by cardiologists [22-24]. The proposed system, an augmented implantable pacemaker, with a TEG system, provides a foolproof system to keep the battery from needing replacement. The system, once commercially implemented and tested, will be an ideal upgrade for the current pacemaker systems. Our design, with the help of VLSI and microfabrication technologies, can be implemented in a smaller or at par form factor as the current industry standard. This will enable the patient to live a worry-free life, knowing that the pacemaker is going to last his entire lifetime. Dagdeviren et al. presented a fully flexible and integrated system that can generate and store energy from the natural contractile and relaxation motions of the heart, lung, and diaphragm at levels that meet requirements for practical applications [25]. The essential modes of operations are revealed by systematic experimental assessments using big animal models and quantitatively precise computational models, which also propose future development paths. They have shown that piezoelectric mechanical energy harvesters (MEH) may generate considerable electrical power from internal organ movements, up to and above levels relevant for actual implant application. In this work, we have proposed an implantable pacemaker using TEG that can act as a source of power that can generate pulses, with enough energy for a pacemaker, from the variations in human body temperature. The proposed device is currently proposed on a theoretical basis.

Even if the proposed device itself may not need replacement, the leads, for the device, when placed at positions that display the range of temperature difference, will end up degrading, and needing replacement. To achieve the temperature difference the leads may need to be placed in such a way that they will undergo degradation. The practical implementation of the device can only happen after detailed design considerations, and extensive testing in vitro, animal testing, and in vivo testing. The dysfunction of the leads has to be studied and they have to be designed in such a way as to minimize their deterioration in the body's extreme conditions. These practical considerations can also be circumvented when the TEG technology itself improves over time, and the temperature difference required to generate the required levels of voltage and current can be generated with a much lower temperature gradient. This lowered gradient will be attainable in the vicinity of the device itself, due to the normal operation of the body. This will eliminate the requirement for the leads to be placed in remote locations, and thus eliminate the need for lead replacement, due to deterioration.

IV. Conclusions

This work, when implemented with a standard pacemaker system is a viable practical upgrade for the current industry standard. The system needs to be practically implemented on-chip, and the prototype needs to be able to perform at par with the current standards. This paper proposes the initial design and deals with the work done towards designing, refining, and verifying the viability of the design. More work needs to be done to bring it closer to the practical implementation of the design. There are various challenge to find the cold source inside the body. The body is an exothermic in nature and it produces heat during its functioning. So there are no cold areas in the body, but it is possible to find a heat differential in the body, where one lead can be placed at an area warmer than other. This difference will determine the amount of output produced by the system.

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