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The Swiss approach for a heartbeat-driven lead- and batteryless pacemaker

Short title: *Heartbeat-driven lead- and batteryless pacemaker*

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Introduction

Active medical implants play a crucial role in cardiovascular medicine. Their task is to monitor and treat patients with minimal side effects. Furthermore, they are expected to operate autonomously over a long period of time. However, the most common electrical implants, cardiac pacemakers - as all other electrical implants - run on an internal battery which needs to be replaced prior to its end of life. Typical pacemaker battery lifecycles are in the range of eight to ten years [1] however strongly depend on the device type and usage. Therefore, many patients are confronted with repeated surgical interventions [2] which increase the risk of complications such as infections or bleedings [3–5] and are costly. Furthermore, the battery accounts for a majority of a pacemaker's volume and weight. Its large footprint demands locating conventional pacemakers at a remote pectoral implantation site. Moreover, the large battery is responsible for another major limitation: to deliver the electrical stimulus at the pacing site, conventional pacemakers require long leads. They are exposed to continuous mechanical stress and are prone to fracture. Especially for younger patients this is a critical factor [6,7].

In brief, batteries are the Achilles heel in the design of cardiac pacemakers. Therefore, an inexhaustible power supply and a leadless design are highly desirable. Different approaches have been investigated to extract energy from various sites and sources of the body [8,9] as for example the knee [10], the chemical reaction of glucose and oxygen in dedicated fuel cells [11], the skin-penetrating sunlight by solar cells [12], the body movements using nanowires [13] or the body heat [14].

The human heart is another convenient energy source for medical implants, in particular for cardiac pacemakers: Regardless of a person's activity, the myocardium contracts in a repetitive manner and thereby reaches high accelerations of ≈ 2 m/s^2 [15], an excellent endurance (> 2.5 billion cycles in a 70 year lifetime) and a large hydraulic power (≈ 1.4 W with mean aortic pressure p_{mean} ≈ 100 mmHg and cardiac output CO ≈ 6.3 l/min [16]). Researchers have been exploring ways to take advantage of this energy source, for instance by harvesting energy from blood pressure differences using a micro barrel [17] or a dual-chamber system [18]. Furthermore, piezoelectric materials [19–22] as well as electromagnetic systems [23,24] have been utilized to harvest energy from the ventricular wall motion.

The automatic clockwork of a wrist watch is an example of a well-established and successful approach to convert human motion into electrical energy. The automatic clockwork captures the motion of a person's wrist during daily activities by an oscillation weight. A mechanical transmission gear and an electromagnetic generator finally convert the oscillations into electrical energy, which powers the wrist watch. Such energy harvesting mechanisms typically generate a power of 5 – 10 μW on average but can get as high as 1 mW depending on the person's activity [25–27]. As a comparison, contemporary leadless pacemakers require less than 10 μW mean power to operate (according to device manufacturers' reference manuals).

The aim of this study is to demonstrate the feasibility of battery- and leadless cardiac pacing using a custom-made pacemaker supplied by an energy harvesting mechanism derived from a reliable Swiss wrist watch. The device's ability to harvest energy from heart motions was tested during experiments with a robot that mimics human heart motions. Finally, the pacemaker prototype was tested during an acute animal trial to show the feasibility of pacing a heart with its own energy.

Methods

Myocardial contractions provide continuous energy in the form of mechanical motion. An energy harvesting mechanism was introduced to convert the heart's mechanical energy into electrical energy. A dedicated electronics was developed to process and store the converted energy and to treat the heart with minute pacing stimuli (cf. Figure 1). As the results will show, during this process, only a small portion (~ 80 μW) of the heart's total energy (~ 1.4 W) is converted and can be used to power the devices electronics. The following subsections describe the energy harvesting mechanism and the pacemaker electronics, as well as the setup for testing the device on the bench and in-vivo.

Energy Harvesting Mechanism

The energy harvesting mechanism is based on an automatic clockwork (ETA 204, ETA SA, Grenchen, Switzerland). The system was adapted to harvest energy from heart motion: time and date indicating parts were removed and a new oscillation weight was developed [28]. The total weight of 9.2 g was achieved by skeletonizing the clockwork's framework. This reduced the energy harvesting system to four main components (cf. Figure 2) with the following functions:

1. The **oscillation weight** translates externally applied accelerations into an oscillating rotational motion. To increase its sensitivity to heart motions the oscillation weight was optimized and redesigned using a mathematical model reported previously [24,28]. The new oscillation weight features a mass of 7.7 g and is made of a platinum alloy (950 PT CO).
2. The **mechanical rectifier** translates the previously described oscillation into a unidirectional rotation. This allows harvesting energy from rotations in both directions.
3. The unidirectional rotation spans a **spiral spring** that temporarily stores the energy in mechanical form.
4. At last, an **electrical micro generator** (MG205, Kinetron B.V., Netherlands) converts a rotational motion into an electrical signal. When the torque of the spiral spring equals the holding torque of the generator, the spring unwinds and drives the electrical micro generator. The resulting impulse comprises about 80 µJ at a load resistance of 1 kΩ.

Pacemaker Electronics

The electronics of pacemakers typically include different features such as sensing, pacing or automatic rate adaptation. Each individual feature consumes energy from the battery and determines the lifetime of the device. Therefore, in the development of modern pacemaker electronics, it is important to reduce the power consumption of the electronics to a minimum. But their lifetime is also determined by external factors: a small tissue impedance, a high pacing threshold voltage, a wide pacing pulse or a high pacing frequency will increase the overall power consumption of a pacemaker electronics.

The here presented pacemaker electronics inherits two main functions that serve the purpose of demonstrating the feasibility of battery- and leadless pacing (cf. Figure 3):

1. An energy management circuit (EMC) receives an alternating current impulse from the micro generator that needs to be rectified. Each such impulse is temporarily stored in a buffer capacity (47 µF capacitor TM8T476K010UBA, Vishay, United States). The voltage level in

the buffer capacity can reach levels between 0.8 V and 6 V, which mainly depends on the actual energy conversion rate of the energy harvesting mechanism for the present myocardial motion.

2. A simple pacemaker circuit (PMC) employs the buffered energy to generate pacing stimuli. Solely relying on the previously harvested energy, the stimulus' voltage amplitude adopts the present voltage level of the buffer capacity (ranging from 0.8 V to 6 V). The pacemaker performs V00-pacing at a fixed rate and impulse duration of 120 bpm and 0.5 ms, respectively. In addition to its pacing abilities, the PMC features a mechanism to inhibit pacing during the implantation procedure.

Assuming the energy harvesting mechanism converts enough energy to provide a constant supply voltage of 3 V, the internal power consumption of the electronics can be measured at 4.2 µW when pacing is inhibited. This internal power consumption is defined by the circuit design, whereas the power for generating a typical pacemaker stimulus (3 V / 0.5 ms @ 120 bpm) depends on the myocardial tissue impedance and can alter over time. Assuming a constant tissue impedance of 500 Ω the pacing stimulus requires an additional 18 µW mean power. Therefore, the energy harvesting mechanism needs to generate 22.2 µW mean power to cover the pacemaker electronics' total power consumption.

Overall Pacemaker Design

The energy harvesting mechanism and the pacemaker electronics are combined in a custom-made housing (cf. Figure 4), manufactured by 3D printing (Alaris30, Objet Ltd., Israel) from polymer (VeroWhite FullCure830, Objet Ltd.). The housing provides six eyelets to suture the pacemaker onto the epicardium of the ventricle. Two pacemaker electrodes are located on the bottom side of the housing and pierce into the myocardium. The stainless steel electrodes measure 0.5 mm in diameter and 3 mm in length. The same pins are accessible from the top of the housing to perform in-vivo measurements of the R-wave amplitude, the pacing threshold and the electrode impedance by connecting a conventional pacemaker programmer (CareLink®, Medtronic, United States). Furthermore, two different metal pins protrude from the lid of the housing, which inhibit pacing when shortcut. For permanent inhibition during the attachment of the pacemaker we used a small permanent ring magnet to shortcut the protruding ends of the pins. By removing the magnet, the pacemaker starts V00-pacing at the predefined frequency of 120 bpm. Finally, a transparent polycarbonate lid seals the housing and allows monitoring the deflection of the oscillation weight. The device weights 12 g, whereas the oscillation weight accounts for 64 % of the total device mass. The housing has an outer diameter and thickness of 27 mm and 8.3 mm, respectively.

Bench Experiment

Prior to the in-vivo experiment, the energy harvesting mechanism was tested on a robot dedicated to mimic human heart motions. The device is mounted on the robot's endeffector platform which is linked by lever arms to six actuating motors. The robot was programmed to mimic heart motion profiles of previously acquired three-dimensional MRI tagging data [24]. The data represents the myocardial motion of the left ventricle over a period of one heart cycle (HR = 85 bpm) of a healthy volunteer in supine position.

During this bench experiment, six different points on the left ventricular myocardium (anterior, left lateral and posterior wall for the apical and basal section) were selected. Sequentially, the robot exposed the device to these motion profiles. The generated mean power for each motion profile was measured over a period of 60 seconds and repeated five times.

In-Vivo Study

The in-vivo experiment was performed on a 60 kg domestic pig. The pig was under inhalation anaesthesia and placed in recumbent position. The trial was approved by the Swiss Federal Veterinary Office and performed in compliance with the Guide for the Care and Use of Laboratory Animals [29]. Thoracotomy and pericardiotomy allowed suturing the pacemaker directly on the epicardium of the left ventricle in an antero-apical position (cf. Figure 5).

Results

Bench Experiment

The results of the bench experiments illustrate high mean output power values, especially for locations on the left side of the human heart (cf. Figure 6). For all six epicardial locations the harvesting mechanism generated sufficient electrical power to meet the demands of modern cardiac pacemakers (< 10 µW [30]). Especially left lateral locations, where the device generated a constant mean output power of 82.0 ± 4.4 µW (apical) and 90.1 ± 0.7 µW (basal), seem to be favorable for the harvesting mechanism. These sites are also most easily accessible by a small lateral thoracotomy. But also at the anterior and posterior-basal locations, the device exceeded the required mean power by a factor of 3 and 5, respectively.

In-Vivo Study

The lead- and batteryless pacemaker was sutured to the antero-apical position of the pig's heart for 30 minutes. The electrode's pacing threshold voltage was measured at 0.9 V / 0.5 ms across a tissue impedance of 1025 Ω at 5 V. The heart movements accelerated the device and resulted in oscillation weight amplitudes of about 90 degrees (cf. supplementary movie). This allowed the harvesting mechanism to extract enough energy to power the internal pacemaker electronics. After removing the inhibitor magnet, the device performed continuous epicardial V00-pacing at 120 bpm (cf. Figure 7, stimulated beats are indicated).

Discussion

We demonstrated that it is feasible to use the heart's kinetic energy to perform cardiac pacing by means of a reliable energy-converting clockwork mechanism. Our approach of gathering energy directly from the heart allowed us to introduce a leadless and batteryless pacemaker.

During bench and in-vivo tests, the device was exposed to physiological cardiac contractions (i. e. normal left ventricular function). It is expected that heart failure has a negative impact on the energy extraction rate of the device. However, the bench experiment illustrated a surplus of energy that might compensate the loss in myocardial contraction.

The implantation of the device on the left ventricle requires a mini thoracotomy which can be achieved by a standard surgical intervention. Alternatively, a catheter-based transvenous implantation could be envisioned for an endocardial fixation at the right ventricular septum. This would require to change the device from a disc- into a rod-shaped design.

The energy supply of the generator is an intermittent signal and not necessarily synchronous with the energy demand of the pacemaker electronics. Therefore, a 47 µF capacitor has been introduced to buffer the generated energy. In case of an energy shortage, this capacity is sufficient to power the pacemaker over a period of 20 to 60 seconds. As a safety precaution for a future medical implant, this storage capacity would need to be increased.

Swiss automatic wristwatches are renowned for their very long lifetime and they have the reputation of being precise and extremely reliable. In daily use, wristwatches are often subject to tough conditions such as high mechanical stress, sunlight that can alter materials (e.g. lubricant or polymeric components) or the exposure to large temperature variations. In addition, aesthetic design criteria further increase the complexity and requirements of today's wristwatches. However, the requirements for an energy harvesting mechanism in future battery- and leadless pacemakers are rather different. Encapsulated in the human body, the device is well protected against sunlight, external mechanical stress and temperature variations. Moreover, without the need to indicate time, the clockwork construction can be simplified to further improve the resistance to wear.

The prototype housing has a very functional design for testing the concept during an acute in-vivo study exclusively. It protects the clockwork and the electrical components against liquids and mechanical effects. Furthermore, it provides a transparent lid and interfaces to the electrical circuit for measuring and controlling reasons. In addition to that, a housing would have to feature hermetic sealing, biocompatible materials and surface treatment to ensure biocompatibility and device functioning for long-term studies.

The current device is designed as a conceptual prototype whereas miniaturization was a secondary objective. The current overall device size (diameter = 27 mm, height = 8.3 mm) and weight could be drastically reduced by changing manufacturing processes (e.g. by introducing application-specific integrated circuits (ASICs)), by using other materials (e.g. exchange rapid prototyping plastic housing by a thin-walled metal housing) or by redesigning components (e.g. housing design that incorporates the clockwork's transmission gear and generator).

The electronics of our pacemaker prototype was built with discrete analogue components. This technique is advantageous for prototyping due to its ease of handling and cost effectiveness. However, it is very limited for designing small low-power applications. By using ASICs, as it is used in commercially available pacemakers and shown by Wong et al. [31], the overall device size and its power consumption can be further reduced significantly.

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Figures

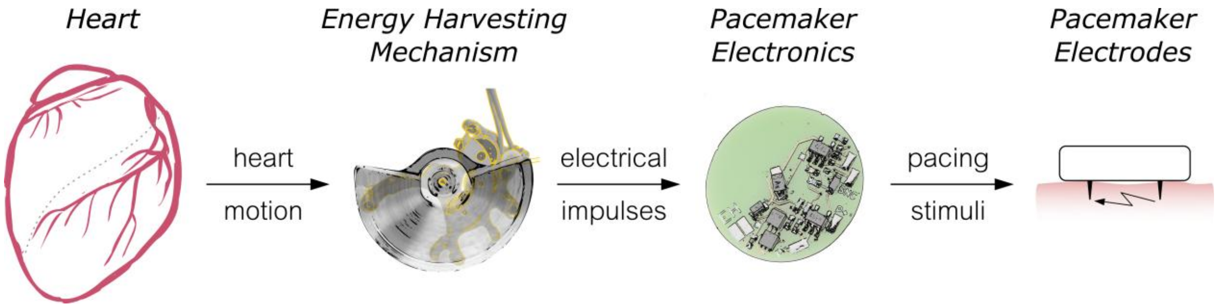

Figure 1: Working principle: The mechanical heart motion is converted into electrical impulses by an energy harvesting mechanism. The pacemaker electronics processes the electrical impulses, temporarily stores the energy and generates electrical stimuli to pace the myocardium with two pacemaker electrodes.

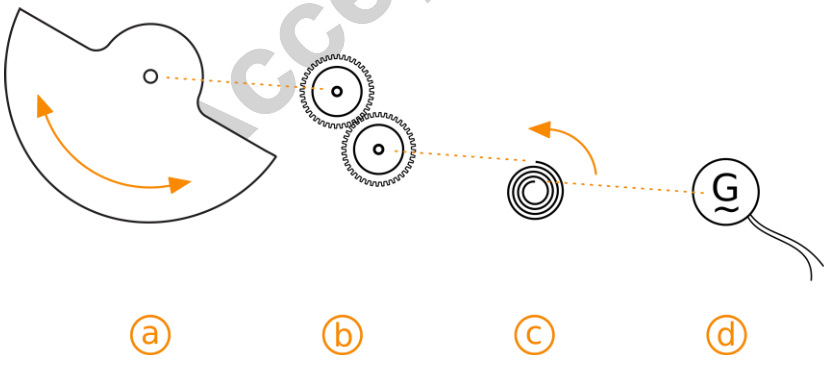

Figure 2: **Energy Harvesting Mechanism**: The schematics of the energy harvesting mechanism illustrating a) an oscillation weight, b) a mechanical rectifier, c) a spiral spring and d) an electromagnetic micro generator.

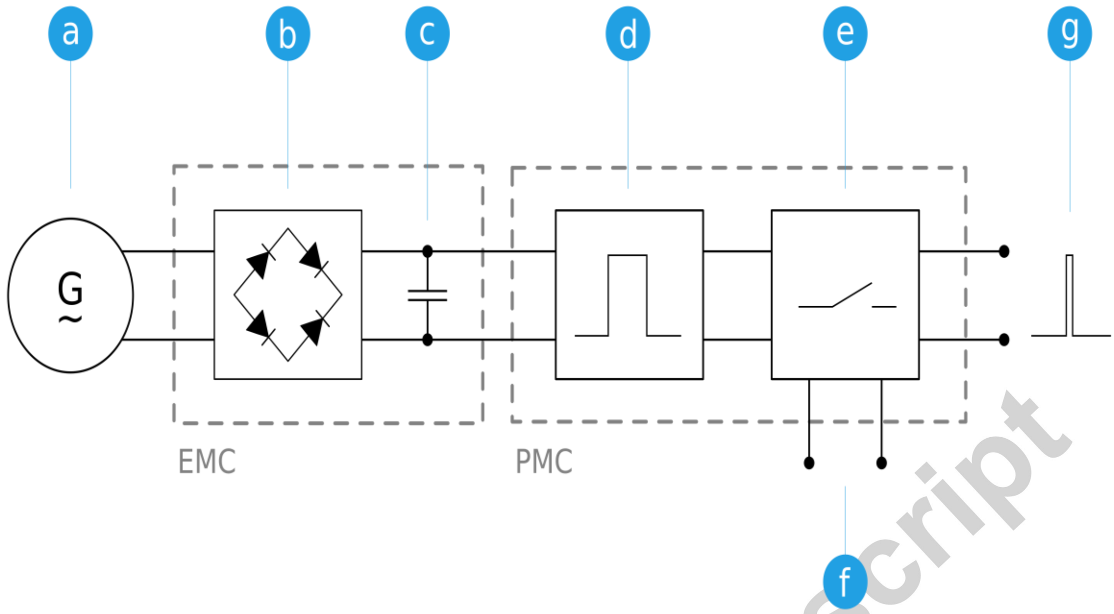

Figure 3: **Pacemaker Schematics**: The schematics of the pacemaker electronics illustrating a) the clockwork's micro generator, b) a bridge rectifier, c) a buffer capacity, d) a pacemaker stimulus generator and e) a switch to apply the stimulus to the heart with f) the option of inhibit pacing by shortcutting the two poles and g) a pacemaker stimulus as output.

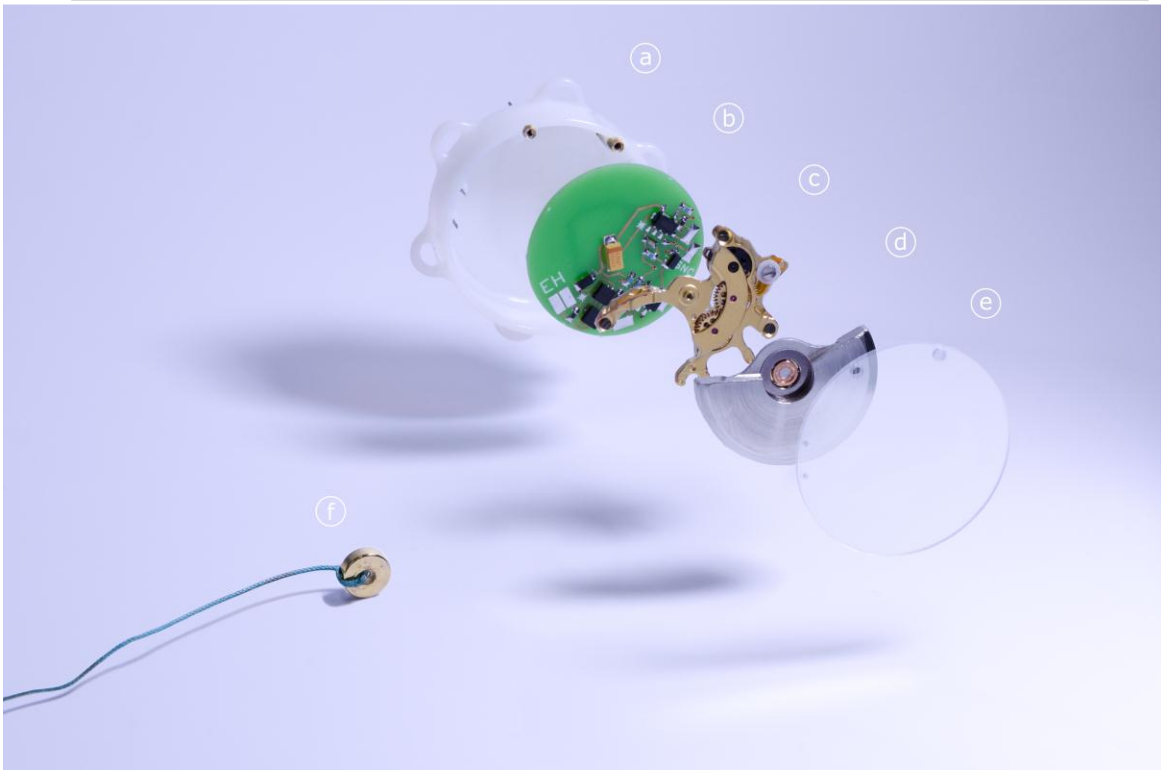

Figure 4: **Disassembled Lead- and Batteryless Pacemaker**: Explosion view of the pacemaker depicting a) housing with pacemaker electrodes and jacks for lead measurement and two metal inhibition pins b) pacemaker circuit c) skeletonized clockwork d) oscillation weight e) transparent lid f) permanent magnet to inhibit pacing.

Figure 5: **In-Vivo Pacing**: Pacemaker sutured on the heart and inhibited by the magnet (cf. supplementary movie).

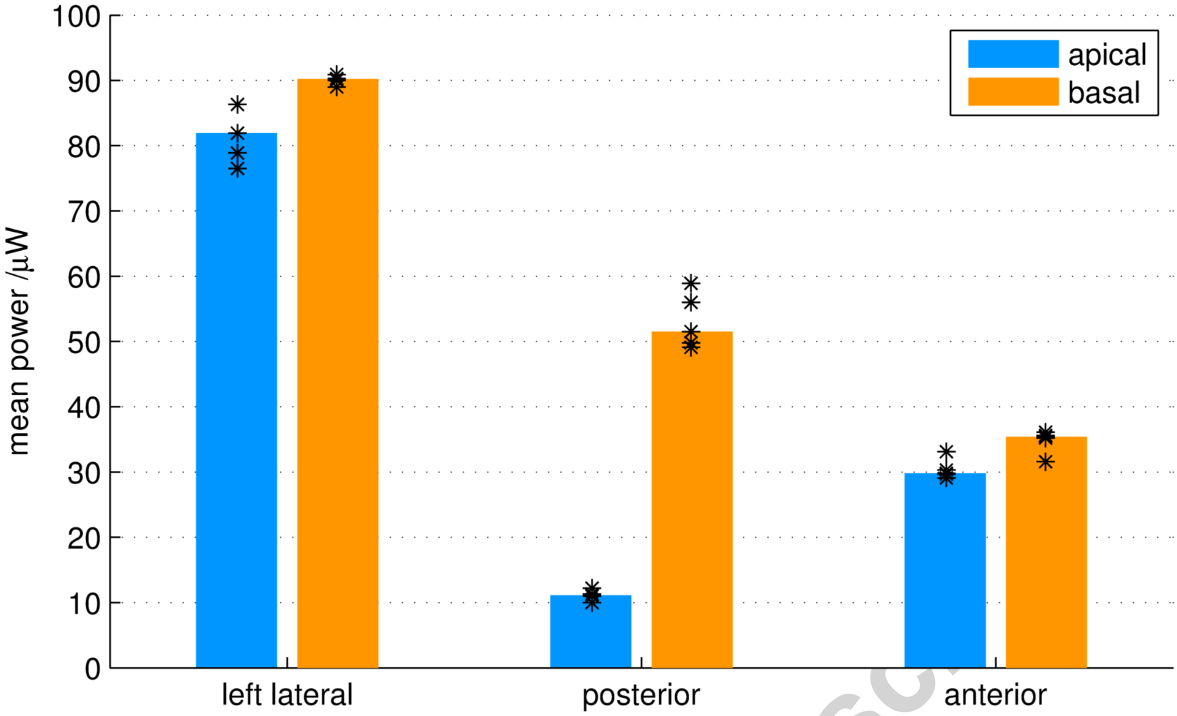

Figure 6: **Bench Experiment**: The power generated by the energy harvesting mechanism when exposed to six different heart acceleration profiles. The five asterisks at each location indicate the generated mean output power of the individual measurements whereas the bar plots represent their overall median value.

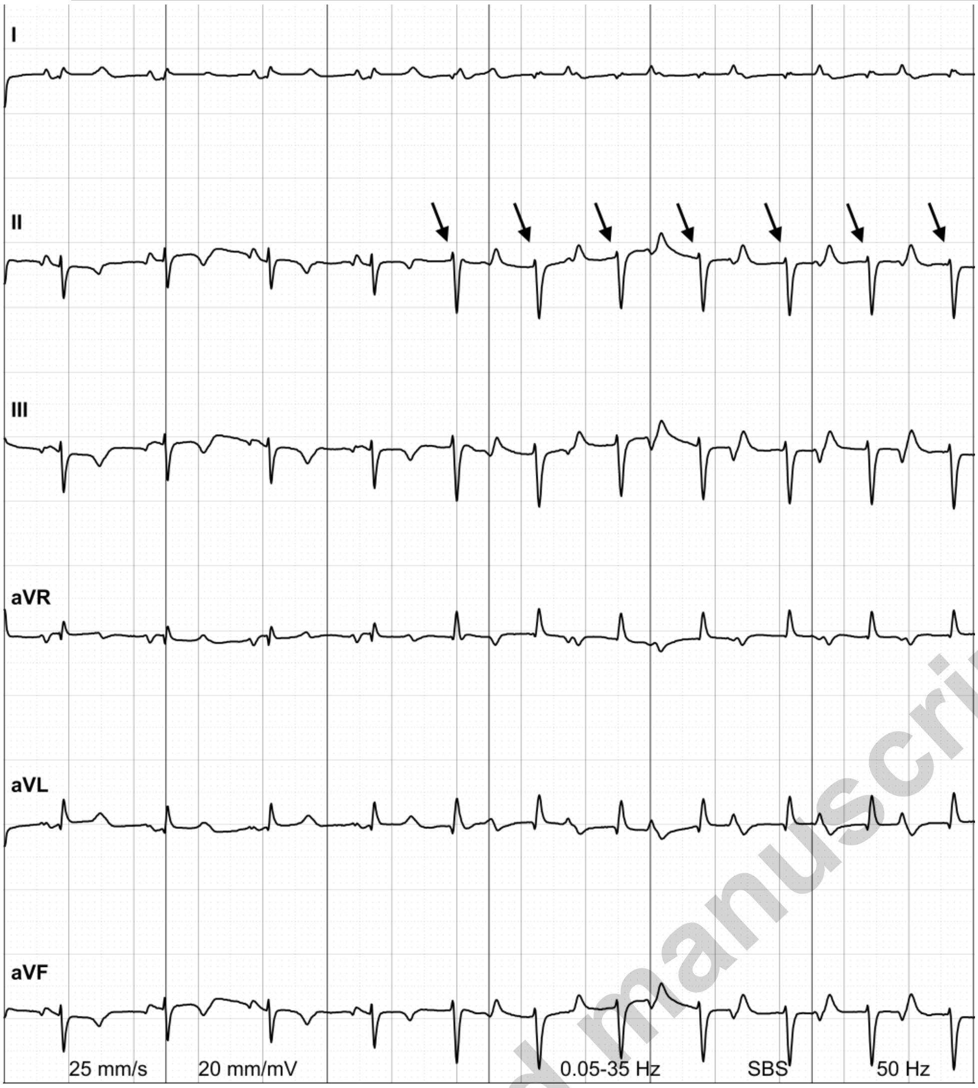

Figure 7: **ECG of Pacing Period**: ECG showing the beginning of pacing (arrows indicate stimulated QRS complexes)