

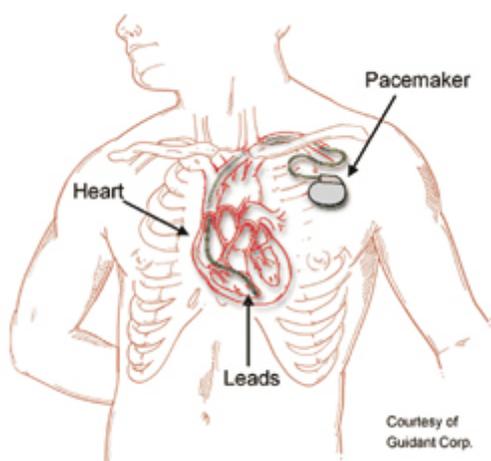
The Power of a Heartbeat

Tracy Wotherspoon and Giles Stanley

In efforts to achieve greater levels of miniaturization for implantable devices, manufacturers are examining every component that goes into them. One of the most common components that impacts the size of an implantable is the battery. This article reviews a technology that utilizes the human heart to generate power for a cardiac pacemaker, significantly reducing the footprint of the power supply.

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Size matters in many situations, and particularly with implanted medical devices. Smaller devices are not as obtrusive, require less complex surgical procedures, and result in faster recovery for the patient.



A significant barrier in the drive towards smaller implanted devices is the battery. Since the early 1970s, the lithium ion primary cell has been the preferred power source for pacemakers. The high energy density of lithium ion coupled with the low power load of the electronics (typically 25 μ W) means the device has a seven to 10 year operating life. However, a typical battery can occupy up to 50% of the pacemaker volume.

While battery size is a concern, at the same time there is an increasing demand for implanted medical devices that can enable more advanced diagnostics and therapies. For example, ultra low-power radios designed into implanted pacemakers are enabling wireless monitoring of device performance and patient health. Although microelectronic assembly processes mean that the area occupied by these additional functions is small, there is a finite space within an implanted medical device. The continuous drive to design less obtrusive and "smarter" implanted

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devices places considerable strain on battery operating life. The question then arises, "How can the battery be made smaller or eliminated altogether?"

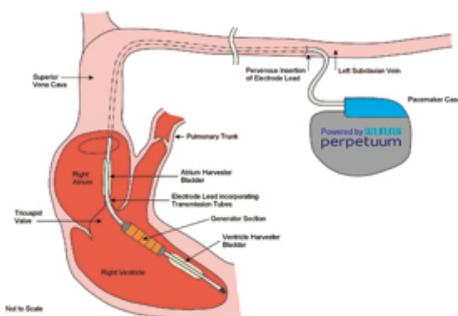
In 2006, a group of engineers and cardiac experts received partial funding from the UK government to find a solution for this problem. The group founded the Self-Energizing Implantable Medical Microsystem (SIMM) consortium and began work on developing a microgenerator that could harvest energy from the human body.

In the early stages of the project, a set of fundamental criteria was established.

The group initially applied these criteria to several energy scavenging techniques, including vibration, piezoelectric, and thermoelectric approaches. All failed to meet at least one of the fundamental criteria. The SIMM consortium eventually settled on a system that uses the differential pressure between heart chambers to drive a linear generator.

Why Does the Device Meet the Criteria?

For the generator to be driven involuntarily, the device must be located to take advantage of body motions that are persistent, regular, and easily accessible. Limb movement or heel strikes, for example, would clearly not meet these criteria. The generator has been designed to extract energy from the involuntary pressure changes caused by contractions of the heart. The patient is totally unaware that energy is being extracted, and the generator will continue to operate during sleep or a state of unconsciousness.



The pacemaker implantation procedure is usually performed by surgeons under a local anaesthetic. It was deemed unacceptable to have any additional procedures in order to insert the device. During the standard percutaneous procedure, the electrode pacing lead is passed through the subclavian vein and into the right side of the heart.

The generator has been designed to fit into the pacing lead. By mounting the generator into the electrode lead, it can be inserted, positioned, and activated using the same procedural steps that are currently used in the insertion of a conventional pacing lead. The surgical implantation procedure remains unchanged, with the small addition of a pre-closure test of the generator output adding a maximum of

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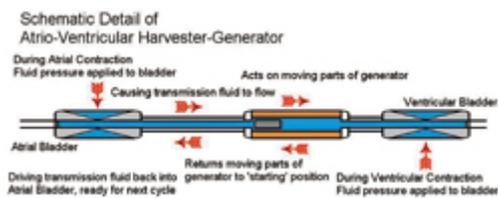
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five minutes to the procedure time.

In order to supplement the power requirements of a pacemaker, the generator must produce over 25 μJ of energy per heartbeat (25 μW at 60 beats per minute). Current EM simulation and mathematical modelling shows that the generator will produce around twice the amount of energy per heartbeat than is specified as useful. Lab testing, using a mechanical heart simulator designed for the SIMM project, has shown that the simulation and modelling data is accurate and trials have shown the efficacy of the energy harvesting method employed.

Calculations on the source energy capacity, namely the energy used in contracting the heart per beat, shows that the device takes less than one percent of the energy used in heart function. Trial results and observations also suggested that no extra stress was placed on the heart when the device was in place and active.

Description of Operation



With current pacemakers, the implant procedure is used to feed, locate, and secure a pacing electrode lead into the right ventricle (and right atrium if needed) of the heart. The lead is inserted into the vascular system through a percutaneous incision in the left subclavian vein, below the collarbone. The lead is guided along the subclavian vein, in and through the right atrium and tricuspid valve, into the apex of the right ventricle.

The pacemaker (with integrated battery) is placed under the skin below the left collarbone.

In integrating an energy harvesting generator into the pacing lead, access to the regular, persistent, and involuntary motions of the heart has been gained. The harvesting mechanism uses the differential pressures seen between the atrium and the ventricle to drive the generator to produce electricity. This power is fed back up the pacing lead to supply the pacemaker.

The function of the heart is regular, persistent, and cyclical, making it a suitable location to harvest energy from the human body.

Key Challenges

Previous lab testing has shown that 'energy soak' in the bladder material has a significant impact on the efficacy of energy harvesting from the heart. Many of the

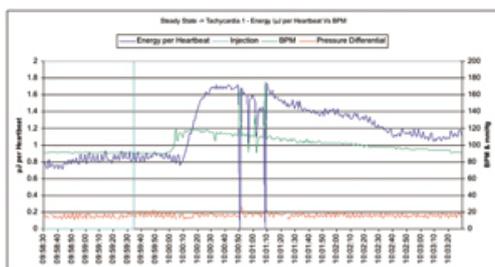
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common biocompatible materials have been shown to exhibit this problem. Current development is focusing on the material selection of the harvesting 'bladders' and a suitable material has now been found.

The narrow pacing lead must carry the stimulation electrodes wires and any wiring required to pass captured energy back to the pacemaker. To reduce the amount of wire being taken from the generator to the pacemaker, it was decided to rectify the generator output waveforms locally. In order to achieve this, a very small multi-channel rectifying ASIC was designed that could be mounted onto the generator.

Early Prototype Test Results



The chart shows the effect of changing the heart function pattern on the energy output of the generator. The heart starts in "steady state" at approx 90 beats per minute and a 19 mm Hg pressure differential (between atrium and ventricle). Following stimulus to increase the heart rate (vertical blue line), both the heart rate and the generator output can be seen to increase (green and dark blue lines respectively).

The results clearly show a significant increase in output with an increase in the heart rate, a correlation that also follows the subsequent restoration of normal heart rate.

The artifacts in the middle of the chart are from sudden and non-persistent increases in heart rate where the generator mechanical function is not able to match the sudden changes in heart rate. However, this also shows that the device is able to quickly "recover" from such episodes, returning to a stable output within one or two beats.

Next Steps

The SIMM project is currently testing its latest generator prototype, which simulations have predicted will generate significantly more power than the mandatory 25 uW. In the next stage of testing, the device will power a real pacemaker using a mechanical heart simulator.

Following successful bench testing, the SIMM consortium aims to produce a clinical version of the device (as opposed to the engineering versions used to date). The

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objective is to prove that the device can be packaged in a manner suitable for surgical use, while maintaining its performance characteristics.

References

¹Webster J.G. et al *Design of Cardiac Pacemakers*, Piscataway New Jersey, IEEE Press 1995.

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com [3] and the following websites:

- www.zarlink.com [4]
- www.perpetuum.co.uk [5]
- www.implantgen.org [6]

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