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The Search for High-Impact Diagnostic and Management Tools for Low- and Middle-Income Countries: A Self-Powered Low-Cost Blood Pressure Measurement Device Powered by a Solid-State Vibration Energy Harvester

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The World Health Organization has established recommendations for blood pressure measurement devices for use in low-resource venues, setting the “triple A” expectations of Accuracy, Affordability, and Availability. Because of issues related to training and assessment of proficiency, the pendulum has swung away from manual blood pressure devices and auscultatory techniques towards automatic oscillometric devices. As a result of power challenges in the

developing world, there has also been a push towards semiautomatic devices that are not dependent on external power sources or batteries. Beyond solar solutions, disruptive technology related to solid-state vibrational energy harvesting may be the next iterative solution to attain the ultimate goal of a self-powered low-cost validated device that is simple to use and reliable. *J Clin Hypertens (Greenwich)*. 2015;17:644–650. © 2015 Wiley Periodicals, Inc.

GLOBAL HEALTH AND CLINICAL BACKGROUND

The global burden of hypertension is increasing substantially. Low- and middle-income countries shoulder 80% of the burden of hypertension-related disease,¹ manifested as a disproportionate prevalence of stroke, heart failure, and renal dysfunction. Hypertension-related disease is also the second leading cause of maternal mortality worldwide.² Unfortunately, those low-resource countries have access to only 10% of global resources to effectively manage the disease and its associated complications.^{3,4}

The common thread for all hypertension-related activities is the ability to be able to take an accurate blood pressure (BP) measurement. This stretches from screening of BP as a biomarker, to the diagnosis, prognosis, and management of hypertension as a disease, and finally extending to epidemiology and research. Hypertension is a worldwide public health problem, and the challenge to demonstrate reliable and reproducible BP measurement is universal. It demands a bifid approach of education and training, coupled with appropriate technology support.

In the developed world, within the “chain of community of BP control,” it has been clearly recognized that the key is good BP measurement.⁵ Excellent guidelines have been developed for the management of hypertension in the global community, including the recent American Society of Hypertension/International

Society of Hypertension (ASH/ISH) guideline for management of hypertension in the community.⁶ The World Health Organization (WHO) Cardiovascular Disease (CVD) risk management package for low- and medium-resource settings for assessment and clinical management is stratified by cardiovascular risk.^{7,8} It has been stated that “availability of reliable BP measurement devices (BPMs) was considered to be a prerequisite for implementation of the package under all levels of resource availability.”⁹

MOTIVATION

Despite multiple published international education, training, and technical standards, there have been widespread and well-documented difficulties in the ability to take an accurate and reproducible BP measurement.^{10–13} Presently, low-resource-driven cost decisions have contributed to a predominance of unreliably calibrated aneroid manual BPMs in low- and middle-income countries. Reliable diagnostic accuracy is further complicated by the pragmatic reality of inconsistent knowledge and skills acquisition using auscultatory technique across the spectrum of providers.

From the technology perspective, manual devices and auscultatory technique have a long tradition. The use of a self-powered circumferential cuff goes back to the described developmental reports of Scipione Riva-Rocci using a mercury manometer and palpatory technique in 1896. Auscultatory technique, and defined sounds to classify systole and diastole, goes back virtually unchanged to the classic work of Dr Nicolai Korotkoff in 1905. Improvements in technology and costs in the developed world have contributed to increasing acceptance of automatic and semiautomatic devices using oscillometric technique with defined

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standards of performance. Unfortunately, low-cost automatic devices used primarily for home BP monitoring are not robust enough for heavy clinical use. In addition to cost, a fundamental problem that limits utilization of these automatic devices in many parts of the world is the fact that electricity is not available at clinical sites and batteries are often unaffordable. Innovative means for powering and operating these BP devices are required.

WHO has addressed the issue of affordable technology related to BPMDs for low-resource settings, establishing an expectation that they should be accurate, affordable, and easily available. Specific recommendations have included that devices be clinically and technically validated as to accuracy.¹⁴ Semiautomatic devices that decrease power needs, including potential flexibility to be used for manual auscultatory technique if the oscillometric measurement component is disabled or turned off, are preferred. Technical specifications were recommended, including electronic transducers, solar power, digital display, and performance requirements, which should address the need for robust bulb inflation system for high patient loads. A retail cost target was to be less than EU €20 in 2002.¹⁵

In response to this challenge, the Omron HEM-SOLAR device (Omron Healthcare, Inc, Lake Forest, IL) was then developed and tested for use by nonphysician health care workers in Uganda and Zambia with some challenges related to diastolic accuracy.¹⁶ Diastolic accuracy has also been a particular challenge for the technology opportunities related to preeclampsia and focus of the Merck for Mothers Program.¹⁷ The diurnal concordance of solar charging and high-frequency clinic use has for some been a logistical challenge (the Omron HEM-SOLAR device was rated for a 300 inflation capability.) A rotating solar-powered multi-battery system, potentially also charging cell phones, has been used as somewhat a variation on the WHO solar battery-less theme. Preliminary efforts have also explored cell phone technology-mediated BP measurement systems.¹⁸

A policy statement of the World Hypertension League on noninvasive BPMD recently issued the recommendation for preferential use of semiautomated or fully automated oscillometric BP devices in both the developed and developing worlds.¹⁹ A forthcoming statement on global BP screening will confirm that recommendation. The ASH/ISH management of hypertension in the community guideline had a similar call for the use of these automated devices because of their ease of use by a broad spectrum of appropriately trained health care professionals.

Such a “call to arms” requires the development of high-impact tools specifically focused on components of self-powered semiautomated oscillometric design, reliability as defined by international validation standards, with low financial and associated training costs.

BACKGROUND OF VIBRATION ENERGY-HARVESTING TECHNOLOGY

Continuing technological improvements such as reduction of cost, size, and weight of electronics in general enable their use in almost every synthetic or biological system. However, the energy limitation of portable energy storage and power sources is still the fundamental bottleneck for virtually all applications, including BPMDs. In this context, the ambient energy from solar loads, wind loads, thermal gradients or mechanical vibration in structures, and vehicles can be harvested and used to provide the energy needed for portable electronics. Reviews of the literature on energy harvesting are given in Sodano and colleagues,²⁰ Anton and colleagues,²¹ Cook-Chennault and colleagues,²² and Priya and Inman.²³ Furthermore, focused reviews on the topic of broadband vibration energy harvesting have recently been presented by Pellegrini and colleagues²⁴ and Harne and Wang.²⁵

In the past decade, compared with other energy-harvesting schemes, vibration energy harvesting using piezoelectric materials has been the most popular method for applications in electrical, aerospace, and mechanical engineering disciplines. Compared with electromagnetic, thermoelectric, and photo-voltaic energy conversion methods, a complete electromechanical conversion system can easily be implemented on a micrometer, or even smaller, scale. The fundamental benefit of a piezoelectric material-based vibration energy harvester is its “solid-state” nature, which makes it possible and sometimes practical to implement in small systems or subsystems that require relatively low levels of power. Devices in the form of “solid-state” cantilevered beams, or its derivatives, have been proposed and accepted as the modern alternative to the well-known electromagnetic generator to harvest energy from vibrations.

There has been a significant research and development effort for the purpose of enabling smart materials for energy harvesting in applications ranging from battery-free pacemakers (see Karami and Inman²⁶) to structural health monitoring of civil or aerospace structures (see Beeby and colleagues,²⁷ Priya,²⁸ Lefevre and colleagues,^{29,30} Friswell and colleagues,^{31,32} and Borowiec and colleagues³³). Piezoelectric materials can sense and harvest from mechanical stimuli as well as producing mechanical actions. The energy-harvesting performance of single-crystal and polycrystalline piezoelectric materials have been examined by Erturk and colleagues,³⁴ Karami and colleagues,³⁵ and Bilgen and colleagues.^{36,37}

SELF-POWERED LOW-COST BP MONITOR CONCEPT

The use of piezoelectric composite (piezo-composite) cantilever beam(s) submerged in the flow induced by the manual pumping of the bulb is proposed to power a self-powered BPMD. The proposed concept for harvesting

energy is very simple. First, the air flow caused by inflation of the cuff is allowed to pass over a piezo-composite beam placed in a harvesting chamber. The beam consists of a piezoelectric (transduction) layer bonded on a typically metallic substrate; hence, the name “piezo-composite.” The passing air flow induces vibrations on the cantilevered beam similar to the effect of wind on a flag. The mechanical vibrations of the beam are harvested (transformed) by the piezoelectric transducer attached to the metallic substrate. The electrical charge generated by the piezoelectric layer is stored to a capacitor (an electrical storage device) through a series of conditioning circuits. Each manual pumping action increases the electrical charge stored in the capacitor until the charge reaches a desirable threshold. In analogy, this electrical charge storage is the same as the inflation of the cuff with air by the pumping action of the user. The size of the piezoelectric transducer is selected so that when the cuff is fully inflated, a sufficient amount of electrical energy is stored in the capacitor to enable necessary functions such as the transduction of pressure, the following postprocessing and analyses, and the display and storage of BP data. The concept is illustrated in Figure 1.

It should be noted that the proposed concept for harvesting energy does not change the BP measurement system (ie, electronics) in terms of accuracy, reliability, or certification in any form. The energy-harvesting module can be thought of as a direct replacement for batteries; however, unlike batteries, no replacement will be necessary throughout the life of the device. Completely eliminating electrochemical batteries in a commercial electrical device has significant benefits in several areas such as product certifications in safety, risk of operation, storage, and disposal. Including the

piezo-composite transducer, all electrical and mechanical components of the proposed energy-harvesting module can be mass-produced using common integrated circuitry–manufacturing techniques as these components have been part of consumer electronics (eg, wired phones and mobile electronics) for decades.

RESEARCH GOALS AND OBJECTIVES

The research endgame is to increase the availability of low-cost accurate and reliable BP monitoring systems for BP measurement and screening worldwide. To this end, the research seeks to develop and employ a system-level theoretical framework that will be used to model and optimize the behavior of the proposed self-powered BP measurement system. The primary objective is to demonstrate the feasibility of a self-powered (potentially semiautomatic) BPMD. Self-powering of the system will be achieved by the use of vibration energy harvested with a built-in solid-state piezoelectric transducer. To the best knowledge of the authors, a low-cost solid-state self-powered BP monitoring system has not been demonstrated.

The demonstration of the feasibility of the proposed self-powered semiautomatic BPMD will require a multiphase investigation that is ongoing. Phase I, which the current investigation deals with, aims to develop experimental data to prove that adequate vibrational energy can be harvested in order to power present standard state-of-the-art, commercially available, semiautomatic BPMDs. Phase II will begin to engineer appropriately sized components with the goal of attaining the most cost- and power-efficient solution as a standard for low-resource areas. Phase III will test the mechanical solutions necessary for a robust bulb inflation system that will stand up to heavy repetitive use. Phase IV will

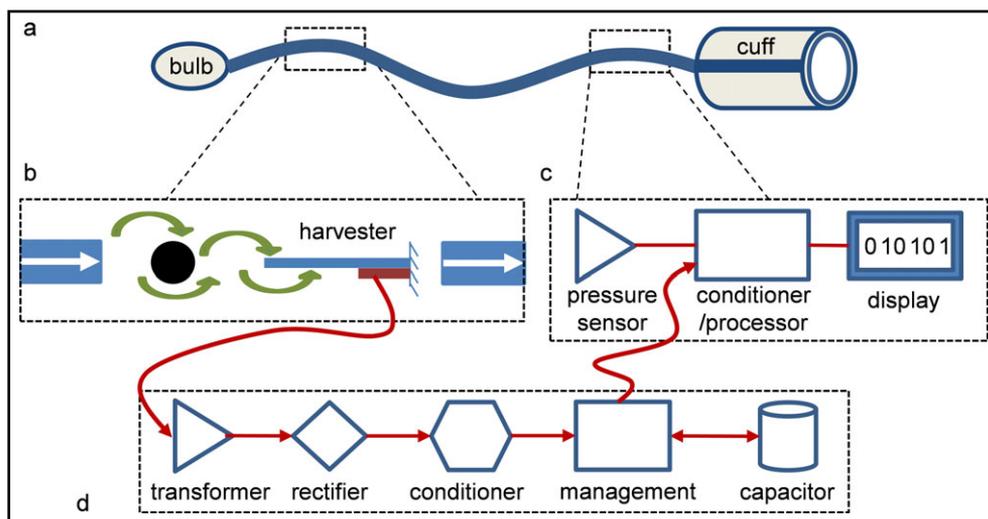


FIGURE 1. Self-powered semiautomatic blood pressure (BP) measurement device. Conventional bulb and cuff (a), proposed flow-induced vibration energy harvester (b), conventional electronics for measurement and display of BP (c), and conventional power electronics for conditioning and storage of harvested power (d).

develop a prototype that will be used in limited clinical trials in a controlled spectrum of domestic clinical office and urban/rural sites in Haiti. Phase V will require rigorous testing of devices according to WHO/DABL established criteria.

In order to achieve the primary research objective, the current preliminary feasibility analysis (phase I) must focus on two questions. (1) Does the difference of power requirement between automatic and semiautomatic devices confirm the rationale that semiautomatic devices are the preferable solution? (2) Does the concept of energy harvesting from vibrations using solid-state piezoelectric materials allow for adequate power generation for state-of-the-art, commercially available, semi-automatic devices. The answer to both of these questions will be presented in the following sections.

ENERGY HARVESTING FROM VIBRATIONS

The power output of the proposed concept is studied by measuring the voltage (and current) output of a piezo-composite beam subjected to known levels of vibratory excitation. A total of 12 piezo-composite representative beam samples were fabricated and tested and the detailed properties of these specimens are presented in Bilgen.³⁸ The experimental setup is shown in Figure 2.

The piezo-composite beams are mounted in a cantilever fashion and are shaken (vibrated) through their base. This method of mechanical stimulation is commonly used to simulate the effect of airflow passing over the proposed cantilevered beam in the energy-harvesting chamber. Figure 3 shows the power-to-base acceleration relationships that are calculated from the experimental measurements conducted on the 12 specimens.

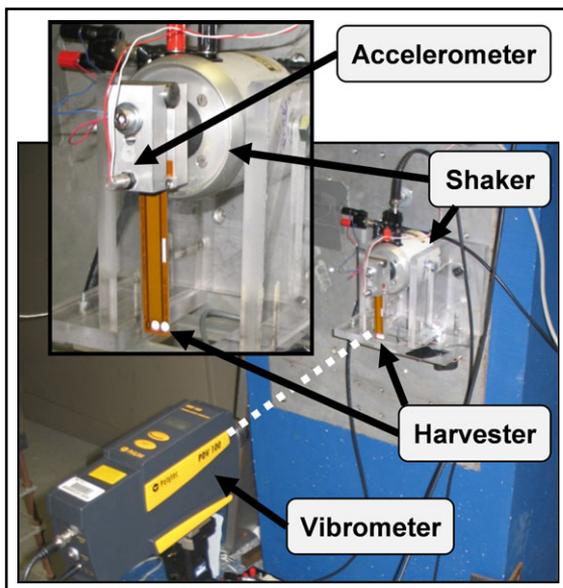


FIGURE 2. Vibration energy harvesting experimental setup for piezo-composite cantilevered beams. The power amplifier for the shaker is not shown.

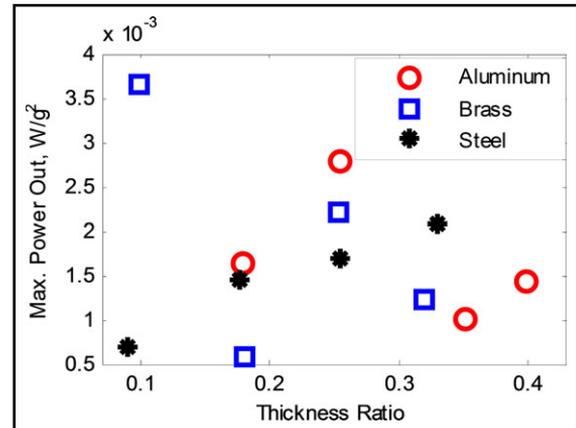


FIGURE 3. Power-to-base acceleration as a function of substrate material and thickness for 12 specimens.

Each specimen has different structural composition and characteristics such as the thickness ratio (ie, the thickness of the piezoelectric layer vs the substrate layer) and the substrate material.

On average, 2 mW/g² of power can be generated by the specimens considered in this preliminary experiment. From these results, it is clear that various levels of power can be generated from mechanical vibrations as a function of the base stimulation (acceleration) amplitude, which is an independent variable used to simulate the air flow generated during cuff inflation. One can change (ie, increase) the inflation rate to change the power generation by the proposed energy-harvesting module. Alternatively, or in parallel, the proposed energy-harvesting system can be scaled to fit various size and weight constraints as well as meeting minimum power requirements.

COMPARISON OF COMMERCIAL BPMDs

In the previous section it was shown that a piezo-composite cantilever beam can produce various levels of power in response to mechanical stimulation and that a vibration energy harvester can be sized to produce virtually any level of power where the size of the device and amount of the piezoelectric material is directly related to the amount of power output. Now, one must examine the system to be powered so that the size of the energy harvester is appropriately selected so that other constraints such as cost and weight can be satisfied. In this context, two commercially available BPMDs are examined for their power consumption so that an appropriate size for the energy harvester can be selected. The first device considered is the semiautomatic Omron Manual BP Monitor (Figure 4).

The semiautomatic device is of interest because of its (assumed) low-power requirement when compared with fully automatic devices because the inflation of the cuff is conducted by the user. The inflation process, mechanically speaking, moving a fixed volume of air against

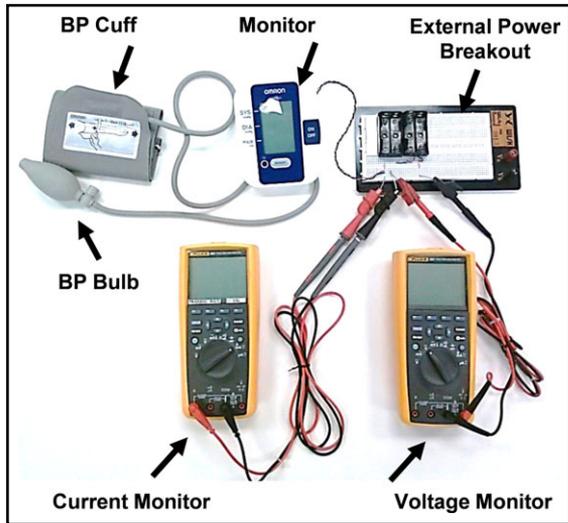


FIGURE 4. The semiautomatic Omron manual blood pressure measurement device prepared for voltage and current measurements. Voltage and current are monitored using two multimeters.

adverse pressure gradient, requires an appreciable amount of energy. In addition to the manual BP monitor, an automatic Omron 10 Series BP monitor is also considered (Figure 5).

In contrast to the semiautomatic device, the automatic BP monitor carries all BP measurement functions using the power from four AA type batteries. Although several hundreds of measurements can be taken using one set of batteries, each measurement is primarily

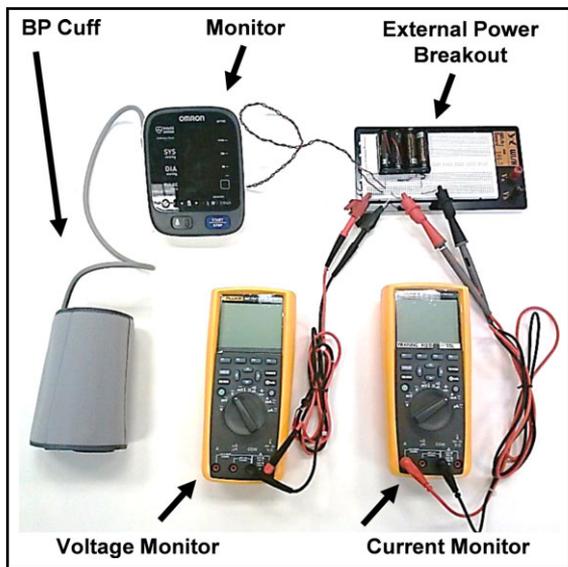


FIGURE 5. The automatic Omron 10 series blood pressure measurement device prepared for voltage and current measurements. Voltage and current are monitored using two multimeters.

limited by the speed and reliability of the motor inflating the cuff. Both in theory and in practice, the commercial-grade fully automatic device may be a low-cost solution; however, it will suffer from long-term frequent usage either in a medical setting or in low-resource environments.

A series of experiments are conducted on both devices to measure voltage and current in order to calculate the electrical power requirement of the devices. The average power, reported in units of watts, is calculated as the product of the current and voltage measured during operation. At fixed intervals, from power-on to power-off states for one BP measurement, the voltage and current are read using two multimeters connected to the external battery pack in series and in parallel, respectively. Each device is tested three times through the full operation cycle.

For the semiautomatic device, the first measurement trial took 55 seconds with the system averaging a current of 6.4 mA at an average voltage of 6.20 V, resulting in a power consumption of 39.4 mW. The second trial lasted 55 seconds with the system averaging at 6.3 mA at 6.2 V, leading to a power consumption of 39.0 mW. The third trial took 40 seconds with the system averaging 6.4 mA at 6.2 V, leading to an average power consumption of 39.4 mW. As a representative test, the results of the third trial are presented in Table I.

For the automatic device, the first measurement trial took 24 seconds with the system averaging a current of 245 mA at an average voltage of 5.85 V, resulting in a power consumption of 1.42 W. The second trial lasted 24 seconds with the system averaging at 213 mA at 5.89 V, leading to a power consumption of 1.26 W. The third trial also took 24 seconds with the system averaging 211 mA at 5.79 V, leading to an average power consumption of 1.20 W. As a representative test, the results of the third trial are presented in Table II.

It is clear that the average power consumption of the automatic device is approximately 40 times higher than the semiautomatic device, and the peak power consumption of the automatic device is 47 times higher than

Time, s	Current, mA	Voltage, V	Power, mW
0	6.3	6.20	39.1
5	6.3	6.20	39.1
10	6.3	6.20	39.1
15	6.3	6.20	39.1
20	6.4	6.20	39.7
25	6.3	6.20	39.1
30	6.4	6.20	39.7
35	6.4	6.20	39.7
40	6.5	6.20	40.3
Average	6.4	6.20	39.4

TABLE II. Results From the Third Trial on the Omron Automatic Blood Pressure Measurement Device

Time, s	Current, mA	Voltage, V	Power, W
0	248	6.00	1.5
3	248	6.01	1.5
6	253	5.71	1.4
9	270	5.68	1.5
12	295	5.61	1.7
15	348	5.50	1.9
18	137	5.70	0.8
21	58.0	5.95	0.3
24	39.8	5.96	0.2
Average	211	5.79	1.2

the semiautomatic device. Theoretically, the semiautomatic device can make approximately 24 times more BP measurements compared with the automatic device when powered by the same set of four AA batteries. This factor takes into account that the automatic device takes 24 seconds to complete a measurement whereas the semiautomatic device takes 40 seconds to complete the same task.

FEASIBILITY OF THE PROPOSED CONCEPT

The experiments conducted on the semiautomatic and automatic BPMDs quantified the amount of minimum power required to carry out all functions. For the commercial semiautomatic device considered, manufactured by Omron, 6.5 mA of current at 6.20 V must be provided to carry out all functions during a BP measurement excluding the task of inflation. The current and voltage requirements resulted in the peak power level of 40.3 mW and the total energy consumption of 1.6 Joules over 40 seconds of measurement duration (deduced from Table I).

Clearly, the power generation appears low at first look; however, first, power output is a function of the size of the piezoelectric patch being used. For example, a harvester twice the width will produce twice the amount of power. In addition, it is also important to note that power generation can occur at various levels (Figure 3) and it is also a function of the input stimulation (eg, base acceleration.) Based on the level of power generation by the piezoelectric beam that is considered in Figure 2, the total time that the harvester should be subjected to the excitation can be calculated by the following basic relationship: $\text{Time}_{\text{charge}} = \frac{\text{Energy}_{\text{required}}}{\text{Power}_{\text{average}}}$. Based on the tested devices, the required energy for the semiautomatic device for one measurement is 1.6 Joules and the average power generation by the harvester is approximately 3.8 mW/g^2 . Subjected to 5-g base acceleration, the time-to-charge value of approximately 34 seconds is obtained assuming that the excitation is continuously provided and that the power conditioning and conversion processes can be done with 50% efficiency

CONCLUSIONS

This paper presented preliminary experimental results from a feasibility study on a solid-state vibrational energy harvesting to achieve a self-powered low-cost BPMD. The proposed concept is discussed and complemented with the basic theory behind vibration energy harvesting using solid-state piezoelectric materials. Commercial semiautomatic and automatic devices are examined for their power consumption and for total time for one BP measurement. A prototype piezocomposite cantilever beam vibration energy harvester is tested for its power-generation capability.

It is found that, indeed, there is a dramatic difference in power consumption when automatic and semiautomatic BP devices from a single recognized manufacturer are compared. Although not reported in this paper, there are also significant variations in power requirements between manufacturers for semiautomatic devices with similar functionality. In addition, the initial research presented in this paper clearly demonstrates proof of concept that vibrational energy harvesting can adequately satisfy the power requirements of a commercial semiautomated BPMD.

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