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A Hands-On Course Teaching Bioinstrumentation through the Design and Construction of a Benchtop Cardiac Pacemaker

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***Abstract*— We have developed a bioinstrumentation course that emphasizes practical application of engineering and biological concepts by having students focus on the development of a single biomedical device: a cardiac pacemaker. In creating their benchtop pacemaker, students learn about and design sensing circuitry, data acquisition and processing code, control system algorithms, and stimulation electronics. They also gain an understanding of cardiac anatomy and electrophysiology. The separate elements of the pacemaker created throughout the semester will be repeatedly tested, re-designed, and integrated with one another, culminating in an emulated pacemaker whose efficacy will be tested on North American bullfrogs. It is hypothesized that the hands-on learning in this course, coupled with the practical application of concepts in the context of a single biomedical device, will enhance students' skills in bioinstrumentation design.**

I. Introduction

Bioinstrumentation skills, i.e., the practical use of basic electronics, signal acquisition and processing tools, and computer programming, are often critical in undergraduate Biomedical Engineering Senior Design projects, where students are called upon to develop new circuitry and/or acquisition systems as components of their design prototypes. More importantly, students need instrumentation design skills comparable to their peers in more traditional engineering disciplines in order to enter competitive post-graduate careers in industry or academia. In this paper, we describe a course that provides bioinstrumentation instruction by advancing a central project through all phases of its development. Undergraduate engineering students learn bioinstrumentation in the context of a model system: a cardiac pacemaker. The pacemaker is an ideal model system because it includes sensing and stimulation, processor-based acquisition, and feedback control. Students will utilize basic circuit theory, electronics, real-time control software and hardware such as MATLAB and an Arduino microcontroller to design and construct an emulated version of a cardiac pacemaker. The focus on a single device model system employs elements of Problem-Based Learning and makes use of the "spiral learning" method, in which a class repeatedly revisits a problem after gaining additional expertise to reinforce concepts, increasing students' investment in their work, and developing a robust problem-solving methodology [1]. It is expected that upon completion of the course, students will have constructed a benchtop pacemaker (PM) prototype that is capable of delivering low energy pulses in response to arrhythmias.

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II. Course Structure

Prior to embarking on this course, students are expected to have completed an introductory circuits class and have had basic instruction in MATLAB. It is targeted at Junior or Senior engineering undergraduates. The course will be taught over a standard 12-week academic term. The pedagogy consists of weekly 50 minute lectures that will complement 2 hr 45 min lab periods. In an effort to emphasize practical experience, some elements of the traditional lectures are shifted to online tutorials, making use of the "inverted classroom" to maximize lab time. Each learning module will address the functional blocks that comprise a cardiac PM (see Table 1). The discrete components of the PM will be revisited throughout the term to integrate the different blocks with one another [2].

TABLE 1 Bioinstrumentation Course Modules and Associated Content

Module	Topic(s)	PM Component
I	Analog Circuitry (Sensing)	Cardiac Electrogram Measurement
II	Principles of Digitization	A/D Conversion
III	Anatomy and Electrophysiology	Excitable Tissue Characterization
IV	Digital Processing & Advanced Programming	PM Algorithm Implementation
V	Stimulation Circuitry (Actuation)	Cardiac Tissue Stimulation
VI	Testing	Cardiac Pacing

The fundamental engineering concepts in these modules will be interspersed with the biological principles critical to cardiac pacing. The lab procedures are structured to strike a balance between guided instruction and open-ended challenges, driving the students to devise solutions to the design issues that arise in creating their devices. Each procedure contains a laboratory challenge, which entails the design and testing of a component of the emulated PM. The class will culminate in an animal testing session where students use their PMs to sense and stimulate the myocardium of pithed North American bullfrogs. The animal testing will allow students to further evaluate the performance of their cardiac PM with respect to the real physiology of a functioning heart.

III. Laboratory Modules

The course modules are designed to provide students with conceptual knowledge of a biomedical device and to acquaint

them with the steps one might take to design such a device. Upon completion of each module, it is expected that the students will have created individual elements that can be combined to form a complete benchtop PM prototype. Prior to embarking on the first module, students are given an introductory lecture providing an overview of cardiac electrophysiology and the basic functionality of an implantable PM (see Figure 1).

A. *Module I – Analog Circuitry (Sensing)*

The first module focuses on the importance of signal conditioning circuitry in biomedical signal measurement. This first module is intended to reinforce circuits concepts, with an emphasis on the practical design of signal conditioning circuitry for sensing the cardiac electrogram. The module begins with a re-introduction to passive filtering using R-C networks. This will be followed by the creation and analysis of low pass, high pass, notch, and bandpass filters of varying order and cutoff frequencies. The students are charged with creating filters that can be used to isolate various components of a simulated ECG signal (synthesized using an Agilent 3320A Function Generator). For example, one of the exercises requires the implementation of a high pass filter that attenuates P- and T-waves while retaining the QRS complexes. This type of filtering would be appropriate for a PM in order to detect ventricular depolarizations while minimizing the compromising effects of DC offset or motion artifacts on the signal.

The module proceeds with a discussion of the utility and design of active circuitry, particularly the design of operational amplifier circuits for signal augmentation and active filtering. Students are called upon to construct and analyze basic monolithic amplifier circuits including: inverting and non-inverting amplifiers, a voltage follower, a comparator, and an instrumentation amplifier. Additionally, they are introduced to the utilization of amplifiers for active filtering, which is important given the relatively narrow bands and requisite gains for cardiac electrogram measurement.

The laboratory challenge of this module is to form the front-end signal conditioning circuitry that will be used to measure the cardiac electrogram from the frog's heart. The circuitry will consist of: a pre-amplifier to perform the differential measurement between bipolar electrodes, filtering (active or passive) with appropriate bandlimits to ensure undistorted measurement of the electrogram, a second stage of amplification to augment the levels and dynamic range of the signal, and a comparator that facilitates analog detection of QRS complexes. The circuit will be initially tested by measuring the ECG from a human subject. Students will revisit this circuit throughout the course to improve its performance within the emulated PM.

B. *Module II – Principles of Digitization*

The next phase of PM operation is A/D conversion, in which the electrogram is digitized and analyzed. In this module, students are re-introduced to fundamental concepts of signal digitization and processing. The primary objectives of this module are for students to become familiar with the time and frequency domain representations of the electrogram and to utilize the frequency content of the signal to sample at an appropriate rate, i.e., satisfying the Nyquist criterion. The students begin the module using the synthesized ECG signal, a National Instruments DAQ module (NI USB-6009), and MATLAB code that they write to control the acquisition and display the digitized signals. Students are able to observe the effects of undersampling on the quality of the digitized ECG and how insufficient sampling rates can result in loss of information, e.g., missed or under-detected QRS complexes. They also evaluate the effects of oversampling on processing time and data file sizes. These exercises demonstrate the practical aspects of signal digitization that will be used for the near real-time analysis of the cardiac signals.

After writing acquisition and display code in the familiar MATLAB scripts, students will utilize GUIs of their own design to acquire and display data. They will set the high frequency cutoff of their analog filter to the observed upper frequency limit of the electrogram, effectively bandlimiting the analog signal. This allows for sampling at a rate appropriate for accurate digitization without under- or over-sampling.

C. *Module III – Cardiac Anatomy and Electrophysiology*

The next module in the course is focused on familiarizing students with the basic principles of excitable tissue stimulation. The benchtop pacemaker is expected to

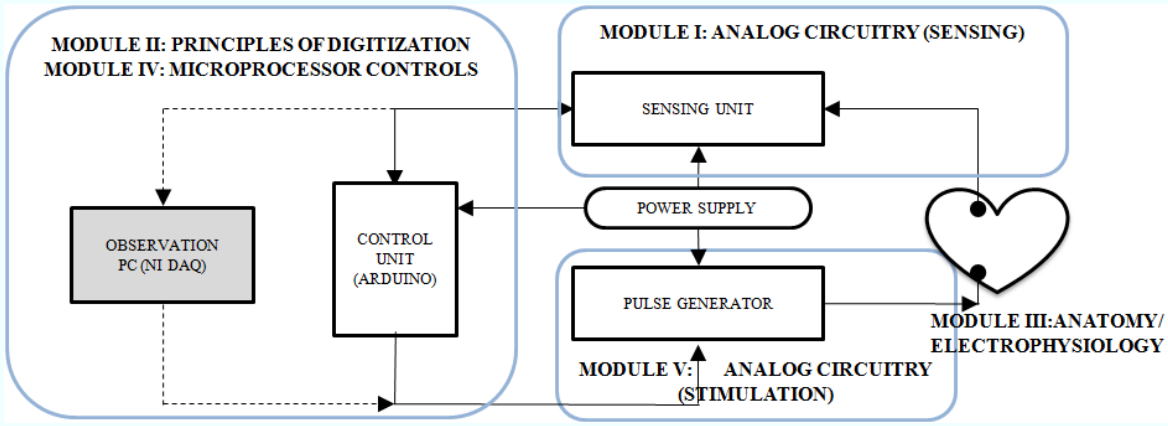

Figure 1. Block diagram of benchtop emulated PM functional components that will be created by students throughout the bioinstrumentation course. As the development progresses, the pacemaker will be controlled by an Arduino rather than a PC to emulate the standalone capabilities of an actual pacemaker.

administer electrical shocks to elicit myocardial contractions. After a discussion of excitable tissues and cardiac electrophysiology, students will conduct an experimental procedure in which they derive a strength-duration curve for frog myocardium. Each student team will perform a dissection of a double-pithed North American bullfrog (all animal procedures are conducted with approvals from Columbia University's IACUC). After exposing the heart, they will insert a concentric bipolar pin electrode near the apex of the heart. The electrode will be initially connected to the analog circuitry created in Module I to determine whether the electrogram can be accurately measured.

After verification of the electrogram measurement, the students will derive the electrical current strength-duration curve using the procedures outlined in [3]. Briefly, the tissue will be excited with rectangular pulses of set duration using a commercial tissue stimulator (WPI IsoStim A320 Isolated Pulse Generator.) Pulse intensity will be progressively increased until a myocardial contraction is observed. The duration is subsequently decreased and the intensity is adjusted until a contraction is elicited. This process is repeated to obtain multiple points, resulting in an approximately hyperbolic current intensity vs. stimulation duration curve. The resultant curve can be used to derive the energy (U) and charge (Q) strength-duration curves for the myocardium. Also, the curves will help students determine the rheobase and the chronaxie of the myocardium, which are used to optimize the PM stimuli. The data that arises from this testing will be stored for utilization in the final benchtop emulated PM.

D. Module IV - Advanced Programming and Microprocessor Controls

To this point in the class, students will have used a computer, MATLAB, and a NI DAQ module to digitize and process cardiac electrical signals. However, this acquisition system is not a realistic representation of a PM, which is typically implantable rather than tethered to a computer. To further emulate the true functionality of the PM, students are introduced to basic microprocessor signal acquisition, processing, and actuation using an Arduino microcontroller. The Arduino and its associated programming platform are presented as an appropriate way to perform the benchtop pacemaker's data acquisition and computations without a direct connection to a desktop computer. A basic version of the Arduino control code will be provided to the students. They will use the Arduino to digitize the cardiac electrogram and the output of their comparator circuit from Module I (which generates a pulse in the event of a QRS complex). The students will modify the Arduino control code so that when a QRS is not detected in a prescribed period, i.e., a minimum desired heart rate is not detected, the stimulator will be allowed to fire, while the detection of the QRS will inhibit firing. This code effectively creates an emulated version of a ventricular sensed and paced, stimulation inhibited PM (commonly known as the VVI mode of operation.)

E. Module V – Analog Circuitry (Stimulation)

The focus of the fifth module is on the creation of stimulatory circuitry that will be used to electrically excite the myocardium. Students will receive instruction on the basics of semiconductor circuit elements, principally the use of NPN and PNP BJTs to create voltage controlled switches that will partially comprise the stimulating pulse circuitry. These elements will allow for the generation of pulses of sufficient duration and intensity to elicit myocardial contractions as determined in Module III. The circuit will be triggered by the output of the Arduino as described in Module IV. In the lab challenge portion, students will work to optimize their pulse generation parameters. They will revisit and reinforce elements of analog circuit analysis from Module I, while investigating the grounding, power supply, and shock hazard concerns of stimulation circuitry.

F. Module VI – PM Implementation and Testing

The course culminates in integrating the components of the benchtop PM and using them to pace a frog's myocardium. The last three weeks of the course will be devoted to benchtop PM refinement. The system will first be tested using a synthesized cardiac electrogram. Students must demonstrate that their benchtop PM is capable of accurately measuring the electrogram, detecting the QRS, digitizing the signal for microprocessor analysis, using the digitized signal to decide whether the stimulator will be inhibited or fire, and producing a pulse of appropriate amplitude and duration. The emulated PM is to function like a VVI pacemaker. The Arduino control code is programmed such that there is a minimum rate, e.g., 60 beats per minute. In the event that a QRS is not detected in a 1 second period, the stimulator is allowed to fire. If a beat is detected within the period, stimulation will be inhibited and the detection window reset. Demonstrated performance of the circuit and control code is displayed in Figure 2.

Once the emulated PM functionality has been demonstrated, it will be used to pace a frog's heart. The frogs will be double pithed and dissected to expose the heart. A concentric bipolar electrode will be inserted near the apex and connected to the input of the sensing circuit and the output of the stimulator circuit. The heart will be paced at 1 Hz, with endogenous activity dictating whether or not the stimulator fires. The heart pacing electrogram data will be recorded and the actual myocardial contractions will be visually monitored for demonstration of pacing. The pacing will be considered successful if a prescribed rate can be sustained for one minute and if the rate of pacing is adjustable.

IV. Discussion and Future Work

We have created an undergraduate bioinstrumentation course that emphasizes the practical design of biomedical signal measurement, feedback control, and tissue actuation. Because students focus on the pacemaker as the model system of interest, the critical elements of bioinstrumentation systems – sensing circuitry, signal acquisition systems, processing algorithms, and stimulation

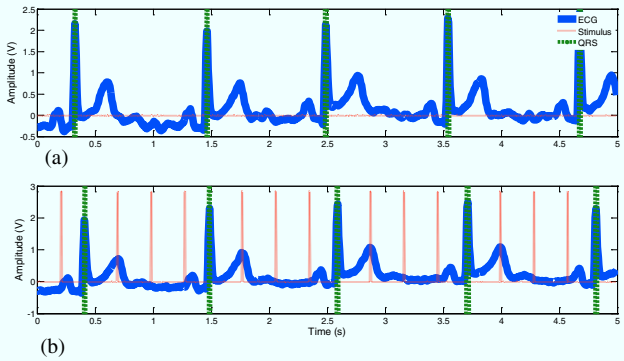

Figure 2. ECG recordings from a human subject (*ECG*) and QRS detections (*QRS*) using course-created circuitry and the associated stimulator pulse trains triggered by the Arduino control code (*Stimulus*). The emulated PM functions in a VVI mode. (a) PM programmed to maintain a minimum rate of 30 bpm, thus the stimulator is inhibited throughout the recording. (b) The PM is programmed to maintain a minimum rate of 210 bpm, resulting in stimulatory pulses and stimulator firings that are inhibited when a natural QRS is detected.

circuitry – are all addressed. While other courses have students design and build instrumentation [4-6], the novelty of our course arises in the instruction of basic electrical engineering precepts in the context of and application to the cardiac pacemaker. Students will be able to approach their design as an integrated system, thus avoiding the knowledge compartmentalization that often arises when they are challenged with applying concepts from previous electrical engineering courses to their BME curricula. We also aim to increase students' familiarity with advanced concepts in bioinstrumentation including the use of a programmable microcontroller for acquisition and response to physiological events. The frog model will allow for implementation of instrumentation in a physiological system.

All of the modules and associated lab procedures have been created and subjected to initial feasibility testing; they are now being revised to enhance inter-module continuity and accessibility to students. The initial evaluation of the course quality will occur via a pilot study. Four electrical engineering undergraduate students of equivalent standing to the BME students that are expected to take this course will act as a test team in a condensed version of the course administered over a six week span in the Spring of 2013. The modules' quality will be evaluated with respect to the following criteria:

- Success of procedures within the allotted lab time,
- Time necessary to complete procedures,
- Documentation of which components are successfully achieved,
- Suggestions on points of improvement, both in the methodology and the nature of the procedures.

The data collected from the pilot offering of the course will be used to refine the laboratory modules. The initial course offering will take place in the 2013-14 academic year. Student evaluations will also be used to continuously refine and improve the course.

In addition to providing training in the practical design of bioinstrumentation systems, a major deliverable of this development process is a set of course materials that is publicly available to other biomedical engineering educational institutions. Laboratory procedures, course syllabus, lectures, and control code will be made available on the MathWorks Classroom Resources website, a large public database of courses utilizing MATLAB. The web materials will be developed during the initial course offering.

While the cardiac pacemaker is an interesting and appropriate device for this class, the instructional methodology proposed herein need not be limited to this device. Other devices that could be appropriate include cardiac defibrillators, neurostimulators, gastrointestinal stimulators, or insulin pumps. Virtually any device that includes sensing, control, and actuation can provide a framework for instrumentation instruction. Additionally, the instruction can be modified such that certain elements can receive more emphasis than others. For example, if a bioinstrumentation course were more focused on electronics and circuitry, then the analog sensing and actuation segments could be expanded, and digital processing could be deemphasized by providing pre-written code to the students. Alternatively, emphasis could be placed on algorithm development and programming, creating a "smarter" PM that could function in more complex sense-stimulation modes or that employ blanking periods to preclude stimuli during tissue recovery (Figure 2b). Also, other real-world aspects of design, such as biocompatibility, electrode-electrolyte interface behavior, power considerations, or telemetry could be incorporated into the class. The practical content in combination with depth of knowledge in instrumentation will facilitate course longevity and ready translation to other undergraduate biomedical engineering programs.

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