31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Honors Biomedical Instrumentation – A Course Model for Accelerated Design

Jai Madhok, Ryan J. Smith & Nitish V. Thakor

Abstract **A model for a 16-week Biomedical Instrumentation course is outlined. The course is modeled in such a way that students learn about medical devices and instrumentation through lecture and laboratory sessions while also learning basic design principles. Course material covers a broad range of topics from fundamentals of sensors and instrumentation, guided laboratory design experiments, design projects, and eventual protection of intellectual property, regulatory considerations, and entry into the commercial market. Students eventually complete two design projects in the form of a 'Challenge' design project as well as an 'Honors' design project. Sample problems students solve during the Challenge project and examples of past Honors projects from the course are highlighted.**

I. Introduction

MEDICAL instrumentation is an important branch of the multidisciplinary field of Biomedical Engineering (BME). According to ABET [1], the recognized accreditor for college and university programs in engineering, applied sciences, computing and technology, upon completion of a bachelors degree in BME a student must have participated in creative, synthetic and integrative activities of design oriented courses and projects. At major research universities where the students have the avenues to engage with scholars from different areas, faculty mentored research and design projects have blended into the core curriculum. Furthermore, undergraduate design experience has proven to be mutually beneficial for students, industry and the field of biomedical engineering as a whole[1, 2].

The course in consideration enhances the ability of students to identify and critically analyze relevant clinical needs, engineer proposed solutions for these needs and then design, develop, test and create a completely packaged prototype of the device within the span of 16 weeks. The target audiences of this are the students in the 'Sensors, Microsystems and Instrumentation' track of BME as well as seniors in Electrical & Computer Engineering (ECE) or the other engineering disciplines. Students are expected to have a fundamental knowledge of circuits, preferably with prior hands on experience through an introductory circuits based laboratory course.

Unlike courses constructed around a year long design project or a culminating capstone experience, this course takes an accelerated approach and requires students to produces two design projects over two separate 4 week blocks in addition to conventional laboratory projects. The highlight of the course is a competition to identify the best design projects. Furthermore, the structure of the course allows students to take on a normal semester load. This paper addresses how such a course can fit into any BME curriculum and covers many aspects of running such a course including an overview of course content, weekly labs and a description of how the two design components are organized. This lecture lab design build compete approach has a multi disciplinary appeal and has been very successful in the past years leading to projects of high caliber and clinical utility, of which some recent examples are highlighted in this paper. The importance of clinically relevant design projects has been highlighted in [3]

J. Madhok and R. J. Smith are with the Department of Biomedical Engineering, Johns Hopkins School of Medicine, Baltimore, MD 21205 USA (e-mail: jmadhok1@jhu.edu; rsmith145@jhu.edu).

N. Thakor is with the Department of Biomedical Engineering, Johns Hopkins School of Medicine, Baltimore, MD 21205 USA (phone: 410-955-7093; fax: 410-955-1498; e-mail: nitish@jhu.edu).

II. Course Structure

The central goal of this course is to equip students with the skills needed for understanding and designing biomedical instrumentation. In order to achieve this aim, the course is structured into four separate components: weekly lectures, laboratory sessions, the Challenge project and the Honors project.

A. Weekly Lectures

These lectures are offered for two hours each week and focus on basic technical topics such as: circuit design principles, instrumentation amplifiers, biopotentials, electrodes, medical sensors, as well as advanced topics such as cardiovascular devices, implantable devices and brain computer interfaces. In addition, another essential component of the lectures is the emphasis on practicality of designs intended for the med tech industry. There are discussions on patient safety, regulatory oversight by Food and Drug Administration (FDA) and classification of devices and their approval, competitive landscape and intellectual property protection. Lectures are occasionally supplemented with relevant speakers from the FDA, industry, and the university's technology transfer office at appropriate times during the semester.

The lectures and the laboratories are highly coupled so that the concepts discussed in lectures are explored hands on in the laboratory. Students' learning and performance in the lecture portion of the course is evaluated through weekly homework assignments or laboratories and finally a technical comprehensive examination. Since much of the technical material is covered in the laboratory sessions and pre lab reports, lecture homework assignments are chosen to encourage students to broaden their knowledge of the field. The exam is typically held later in the semester before the commencement of the 'Challenge' project and covers a range of topics from circuit design to proposing engineering solutions on the fly to selected medical challenges.

B. Laboratory Sections

The lab sessions are to be executed in parallel with the lecture material in order to integrate information, provide hands on experience and to ensure that students are equipped with the skills needed to carry on their independent projects later in the semester. Each lab section is four hours long and requires students to work in pairs to complete hands on assignments relevant to topics discussed in lecture. In the initial lab sessions basic circuit principles including amplifiers, filters and sensors are covered. Next, the more complex design oriented labs cover topics such as the design of a simple temperature controller, strain gauge based pressure or force measuring device, hearing aid and the design of electrocardiography (ECG) and electromyography (EMG) amplifiers.

As the semester progresses, topics covered in lab gradually shift in order to introduce students to systems integration. Topics covered in these sessions include instruction in programming microcontrollers, using commercial sensors, interfacing circuits to personal computers, and transmitting data wirelessly. This series of labs is linked in such a way that the students build a circuit that uses multiple sensors, acquires data, process it using a microcontroller and apply it towards a simple goal. Concepts like Analog to Digital Conversion, Pulse Width Modulation and other elementary digital electronic principles are taught along the way.

Each laboratory session has an associated pre lab and post lab report that is to be submitted. The pre lab report is intended to ensure that students design all required circuits and write any necessary code ahead of time in order to optimize their time in lab. Similarly, the post lab report is designed to assess the student's overall understanding of the material as well as help to develop their ability to present results and think critically to answer open ended design questions pertaining to material learned in the lab.

C. The Challenge Project

Following the completion of the laboratory portion of the course, students engage in what is called the 'Challenge' Project. Students are paired into teams with the intent of solving an interesting biomedical instrumentation problem. Teams are assigned a predefined problem for which they must engineer an appropriate solution. The student teams are challenged to come up with the best solution to the problem and compete with other groups working on the same problem. The projects are designed with a quantifiable metric that is used to assess device performance in a competition that concludes the month long design challenge. The projects are pitched in a competitive sense to inspire innovative solutions and superior performance. The competition mimics the real world in terms of time and resource constraints, encourages team work and fosters competitive spirit. Competition motivated courses have been found to be a have a positive impact on the team spirit and the practical needs of capstone design experiences[4]. Two sample projects and instructions for their execution are described:

1. **Smart Cane for the Blind:**

The objective of this project is to develop a device that provides sufficient feedback for a blind person to navigate through an obstacle course. The device can be manifested in any form but must include at least one optical sensor. Examples of feedback mechanisms include vibration and audible warnings or instructions. The challenge is to design a smart cane that is capable of detecting and navigating amid moving people, low and mid height objects, stairs, and walls/doorways so that a subject is able to walk blindfolded through a custom obstacle course. Teams will be ranked based on their ability to navigate quickly and safely through the obstacle course.

Figure 1 A student navigates an obstacle course using a Smart Cane he and his team developed as a Challenge project

2. **Computer Interface for Quadriplegics:**

Each team will develop a computer interface using one or more bio signals to demonstrate how a quadriplegic may communicate with the world. Examples of bio signals include puffing/sipping, eye motion, or any other relevant signal. The bio signal should wirelessly interface with the computer. The challenge is to use commands from the body to type out a message on a computer and to develop a strategy for the fastest communication of an unknown message (e.g. *Give me an A+*). Teams will race against the clock to see who can reproduce the message fastest. An untrained user will also operate the device to test it.

The challenge project is judged in part on the competition metrics (e.g. the time and accuracy to navigate the course by the 'blind' volunteer or typing out a message) and partly on the overall design, originality, functionality, competition performance, packaging, comfort or convenience of the device and demonstration of effort. If larger teams are utilized, peer evaluations may be performed to ensure each member of the group contributes his/her share of the work.

D. The Honors Project

At the Johns Hopkins University, the Honors portion of the course is offered during the one month of intersession between the fall and spring semesters in which students are not required to take courses. During this time the students work solely on the project, without any additional classes occupying their time. For schools without this gap between the semesters or quarters, the schedule maybe compressed by modulating the labs and having the students begin earlier carrying on into a couple of weeks into the new semester when the work load remains relatively low. The students who want to take the course with Honors are encouraged to start brainstorming clinically relevant ideas right from the start of the semester. Moreover, students are further encouraged to find clinical sponsors and mentors outside the immediate realm of the design course.

The students run multiple ideas in the form of short 2 3 slide PowerPoint presentations with the Teaching Assistants (TAs) and the professor during weekly office hours. These proposals are evaluated on the basis of clinical relevance and technical feasibility given the constraints of time and resources. The students are also given an existing repository of project ideas submitted by clinical researchers, physicians and faculty that have not been used in the previous years. This repository is updated regularly.

The Honor's project is evaluated in two different ways: 1) one by the faculty and the TAs to assess the engineering design, quality of work and the effort that went into each project and, 2) by professionals from academia, medicine and industry who are brought in as external judges to evaluate the innovation, performance, and clinical and commercialization potential. The external judges also share their expertise, experience and provide feedback to the students on their designs. Additionally, in order to emphasize the importance of being IP conscious while carrying out design projects, the students are expected to submit a mock patent instead of a final project report and are encouraged to differentiate their solutions from existing technology. At all steps along the way, students are encourages to get end user feedback.

Like the 'Challenge' project, the finale of the course is in the form of a competition. The judging criteria includes factors like the addressing of a clinical need, patient or physician benefit, innovation, engineering solution, performance, poster presentation and a live device demonstration. The final competition that includes a poster presentation and live demonstration gives the students a holistic feel about the entire design process right from identifying a need to presenting the solution to an audience.

III. SAMPLE HONORS PROJECTS

Projects generated during the Honors design portion of the course run the gamut of biomedical applications ranging from research devices to medical devices providing solutions to clinical problems. A selection of recently completed honors projects is highlighted below:

1. **RFID Integrated Biometric Security Device:** One of the drawbacks of Radio Frequency Identification (RFID) based personnel access systems is the low level of security. If a user loses their RFID tag, the security is compromised for all areas that user had access to. To combat this, a device was constructed that required users to activate and inactivate their card upon leaving a building through use of a biometric access point. Students constructed a scanning device that would verify users based on their hand geometry and then wirelessly transmitted an authentication code to a secure central hub. This communication activated that user's RFID security badge, which could then be used to access a number of secure RFID enabled access points. Upon leaving the building, the users would again make use of the biometric scanner to deactivate their security card. The system was constructed in such a way to easily accommodate any number of additional desired biometric or RFID access points.

2. Incorporation of Haptic Feedback into Teleoperative devices: A teleoperative surgical system was developed to provide force feedback to the surgeon during robot assisted surgery. The system uses two controllers, the first to control a robotic arm for spatial movement (4 degrees of freedom), and the second, a haptic paddle to operate the surgical unit (1 degree of freedom).The surgical unit has force sensors mounted on its tip and wirelessly transmits the forces measured. The wireless force signal is used to produce a proportional analog current which is then amplified to drive a motor affixed on the haptic paddle to provide force feedback to the surgeon. An audio visual console is provided for surgical training, to set the intensity of force feedback, and for providing additional means of feedback.

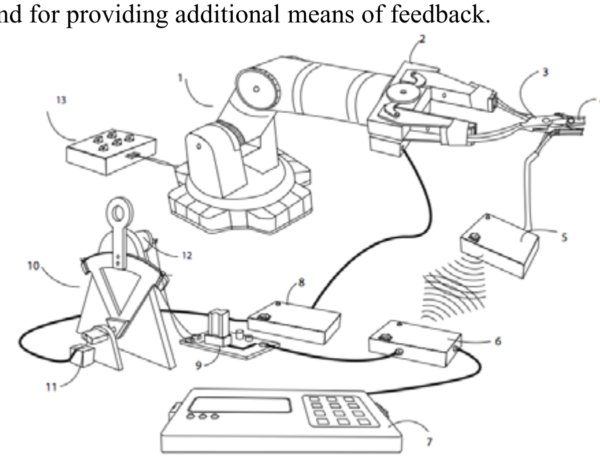

Figure 2 An image from a mock patent developed for a device for haptic feedback for teleoperative surgery is shown here

3. Device for Ultrasonic Monitoring of Pregnant Women during Exercise: The American College of Obstetrics and Gynecologists recommends pregnant women engage in regular, moderate intensity physical activity for 30 minutes or more a day. Despite the obvious benefits, there are several understudied risks associated with exercise like reduced uterine blood flow caused by redistribution of cardiac output and fetal hypoxia. The device consists of a machined ultrasound transducer positioning device, with a range of motion of approximately ±20 degrees in two axes of rotation. The position device is controlled by a joystick in a separate box, which houses all electronics. The mechanical device is robust for repeated use in a research setting. A LabVIEW Program recorded changes in gravitational field relative to sea level, for an independent system to track maternal movement and record time history.

4. Central Venous Pressure (CVP) Monitor: There are presently no broadly available clinical solutions for non invasive measurement of central venous pressure. Students developed a novel handheld probe that works in conjunction with an ultrasound machine to estimate CVP. The handheld probe is used to gently apply pressure to the patient's neck while the ultrasound unit allows the operator to visualize a major vein near the surface of the neck in real time. Using a high precision pressure transducer, this device can quickly and reliably estimate the pressure inside this vein, which can in turn be correlated to CVP.

This particular project is a particularly good example of the quality of design that can be achieved through this course. The student team that designed this project went on to successfully defend their device through several business plan competitions and eventually formed a company to promote the device commercially. This device is under continued development and is currently undergoing clinical trials.

Figure 3 A prototype of a noninvasive central venous pressure monitor developed as a team's Honors project is portrayed

IV. Discussion & Observations

Undoubtedly, the success of this course model hinges on the availability of appropriate resources, both physical and human. Students, for example, must have access to at least a basic electronics laboratory complete with the elementary tools of circuit design and analysis such as oscilloscopes, power supplies and function generators. Access to a machine shop with tooling such as lathe, milling and drilling machines has proven important for producing formal prototypes during the design phases of the course. It is advisable to assign a lab manager capable of management of these facilities for the duration of the course. Ideally, the lab manager would also be available as a resource to students for instruction in basic laboratory skills as well as proper component selection for design projects.

Along these lines, budgeting for expendable components should be taken into careful consideration when planning for the course as well. It is quite possible for expenses to spiral quickly out of control in a course such as this if proper planning is not performed in advance. Traditionally, students are charged a reasonable lab fee that is used to supply them with a basic array of circuit components for completing the laboratory sessions as well as to establish a discretionary budget for each individual team to access during the Challenge and Honors projects. Teams should be made aware of the funds available to them before the onset of each design phase so that the financial considerations may be factored into the design of their projects.

Teaching Assistants (TAs) should ideally be selected from students with ample design experience who can be available to instruct and run the laboratory sessions as well as serve as the primary assistive resource for student teams throughout both the Challenge and Honors design projects. Ideally, if the TA to student ratio is small, each TA may be assigned a number of student design teams to closely mentor. This allows more personalized assistance for each team as the TA is able to have a firm understanding of the challenges the team is facing. However, if there are fewer TAs available, it may be advisable to form a TA pool so as to provide sufficient access and mentoring to all teams.

In comparison with a year long design course this course trains and leads to the development of a prototype within a short focused 4 week duration. The ideas for the projects must be critically evaluated and the students need to mentored so that they understand that the best projects are not necessarily huge complicated designs but may as well be simple ideas executed to excellence. Finding the perfect project that satisfies the various technical, financial and clinical constraints is perhaps the most important aspect of this course. In order to ensure that the students have viable and practical, as well as clinically and commercially relevant ideas to work with maintenance of a design repository is suggested.

V. Conclusion

This course model has been followed successfully at the Johns Hopkins University for almost five years. While some modifications may be needed depending on the availability of various resources, the course structure is modular enough to function well in a variety of configurations. Executed properly, this course gives students the opportunity to learn firsthand the principles of Biomedical Instrumentation while also gaining invaluable experience through the development of two separate design projects.

VI. Acknowledgments

The authors would like to thank Russell Rasquinha, Lindsay Kranker, Jennifer Ferrigan, Vikram Aggarwal, Jim Gwilliam, Terrence Jao for providing project abstracts.

VII. References

[1] Engineering Criteria 2000, Engineering Accreditation Commission of the Accreditation Board for Engineering and Technology.

[2] R. C. Fries, "An industry perspective on senior biomedical engineering design courses," *IEEE Eng Med Biol Mag,* vol. 22, pp. 111-3, Jul-Aug 2003.

[3] J. Goldberg, "Biomedical engineering/industrial design collaboration in senior design projects," *IEEE Eng Med Biol Mag,* vol. 26, pp. 75-6, May-Jun 2007.

[4] J. R. Goldberg, "Providing senior design students with a clinical perspective," *IEEE Eng Med Biol Mag,* vol. 25, pp. 20-1, Mar-Apr 2006.

[5] M. J. Pauli and M. Krishnan, "A competition-motivated capstone design course: the result of a fifteen-year evolution," *Education, IEEE Transactions on,* vol. 44, pp. 67-75, 2001