

## **Integrating Biomedical Engineering with Entrepreneurship and Management: An Undergraduate Experience**

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### **Abstract**

We describe aspects of our cross-disciplinary efforts between biomedical engineering and entrepreneurship and management. Specifically, we describe how these disparate programs are being integrated to encourage interaction between students, faculty and administrators to develop technical prototypes with market potential. In biomedical engineering, a design program is in place where 10-13 teams of 10 undergraduate students each work on independent projects annually posed by sponsors such as researchers, clinicians and individuals in need. The design projects culminate in a prototype and final report. About  $\frac{1}{4}$  to  $\frac{1}{2}$  of these projects have potential for commercial application. In entrepreneurship and management, a program exists where teams of between three and five undergraduate students develop business plans for ideas that are proposed to them by biomedical engineering students. Business plans for projects with commercial potential examine factors necessary to convert the project idea into a viable enterprise. Such issues include market size, revenue and reimbursement, market penetration strategies, costs of operations, legal issues, return on investment, roles of the founding entrepreneurs, sources of funding, harvest strategies, and negotiating deals. To date, four technical teams have successfully collaborated with entrepreneurship teams to generate a prototype and an associated business plan to market a product based on the prototype.

### **1. Introduction**

Within the last two decades, engineering and business educators alike have seen the need to emphasize learning by doing in the undergraduate curriculum [Simon, 1981]. In engineering curricula, this has resulted in a plethora of design and capstone courses [Dixon, 1991], while in business curricula, this has led to a host of courses where students develop their own business plans and interact with industry. With this emphasis on the practical, educators have scrambled to solicit realistic projects from industrial, clinical or research sponsors. One way to ease this scramble is to use realistic projects from engineering as potential projects for those in entrepreneurship and management. This paper describes such an effort and begins with a description of the two programs followed by how they have been integrated.

### **2. Existing Programs**

Over the last five years, the biomedical engineering program at Johns Hopkins University has

developed a set of undergraduate courses called Design Teams. In these courses, teams of students at all levels—from freshman to senior—work together solving problems involving biomedical engineering design. Our main goals in these courses are to 1) teach the design process by providing experiences that mimic that process, and to 2) foster teamwork, inventiveness and innovation. We organize this year-long experience as a pseudo-corporation, Homewood Biomedical Design Associates (HBDA). Within HBDA, faculty and support staff serve as technical management, upperclassmen are project engineers and freshman are new hires. Student teams are made up of a Team Leader, two-four upperclassmen, and five-six freshman. Teams are formed as follows: Team leaders apply to HBDA, are screened by faculty in the Spring and choose their upperclassmen, who also apply to HBDA. In the Fall, the Team Leaders and upperclassmen select their freshmen, who are grouped into sets of three based on nonacademic criteria. In the Fall, new hires are oriented into HBDA by participating in a number of small projects where they often perform themselves. Here, they learn basic skills such as taking measurements, creating mock-ups, making presentations, keeping a journal, writing reports, and performing literature searches; using these skills, freshman can contribute meaningfully to the main project, which is drawn from outside sponsors. Based on their own interest, teams select main projects that faculty solicit and screen from researchers, clinicians and individuals-in-need. Over about six months, teams develop a technical proposal, develop conceptual, preliminary and final designs, construct a prototype and test the design. Our tangible results are these: of the roughly three dozen projects since 1999, more than ½ of the projects are in use by the sponsors, 90% of our customers are satisfied over the long term, all project teams complete a prototype, and our best projects compete in national design competitions. Although biomedical engineering graduates typically do not have business training, industries hiring students with Design Teams experience are pleased that new employees exhibit good leadership, design and presentation skills.

The W. P. Carey Program in Entrepreneurship and Management focuses on business and management from a multidisciplinary viewpoint, with a quantitative emphasis. Typical courses include Financial Accounting, Management Accounting, Business Law, Marketing and Entrepreneurship. The program offers students a diversified learning experience that emphasizes the concepts, practices, and skills necessary for effective leadership as managers and entrepreneurs in the private and public sectors. The primary goal of the curriculum is to provide Johns Hopkins students with the knowledge and skills to become leaders of technology companies, whether in management positions with established companies or in their own new ventures. The program provides students with traditional training in understanding financial reports, interpreting statistical data, organizing and effectively leading a team, analyzing and correcting problems in business operations, and understanding the dynamics of the marketplace. Most courses, even at the introductory level, utilize case studies and projects. Business plans are a common tool in the advanced marketing and managerial accounting classes. To motivate students and to encourage excellence, the university sponsors a business plan competition.

One limiting factor to date has been that business plans have tended to be narrow in focus, working through only a subset of the problems that entrepreneurs face. Alternatively, when students have designed new ventures, they have tended to be of the “pizza truck” variety or have been designed in a vacuum away from the real problems that founders of new ventures encounter. Attempts to have students work at new ventures in conjunction with local businesses have also

not been particularly successful because of the constraints of the semester time-frame and students' lack of practical experience.

### **3. Integrating Engineering and Entrepreneurship**

We began integrating the two programs in 2002, when a biomedical engineering team working on the development of a foot sensing system for a physical therapist, presented their project to a class in Entrepreneurship. One assignment for that class was to develop a competitive analysis for a product; the foot sensing system was one of the products. One student, himself a biomedical engineering student, developed a competitive analysis that demonstrated a potential market niche in the rehabilitation industry. The technical team was able to benchmark better based on the results of the competitive analysis and the business student used the technical aspects of the prototype under development to better understand the market. This interaction between the technical and business students was helpful in obtaining an NCIIA project grant.

Because of the success of this one project, the integration was carried out more formally in the Fall of 2002. Six of the 13 biomedical engineering teams presented their technical projects to a Managerial Accounting class, where one pedagogical goal is to provide Carey Program students practice in creating, evaluating and planning new business ventures, and in converting exciting ideas into viable enterprises. By presenting to the business students, and knowing only three could be selected, technical teams had to focus on more than technical innovation to sell their projects. The projects presented included a birthing simulator, a foot sensing system, a pediatric walker, a tactile sensing system, a system to prevent preterm labor and a tracking system for a handicapped population.

The business teams screened the projects and selected three for development of business plans. The criteria used included product interest, student interest, perceived market potential and technical work accomplished. Interestingly, non-quantitative, personal factors dominated the selection process. The goal was to have students excited to work on the projects and excited to work with each other. Having the BME teams present to the business teams accomplished this objective. The business teams selected the pediatric walker, the foot sensing system and the system to prevent preterm labor. Curiously, the state of each technical project was markedly different. The foot sensing system was designed and had a good existing prototype, the pediatric walker had an existing prototype, but it required complete redesign and the preterm labor prevention system was a new concept.

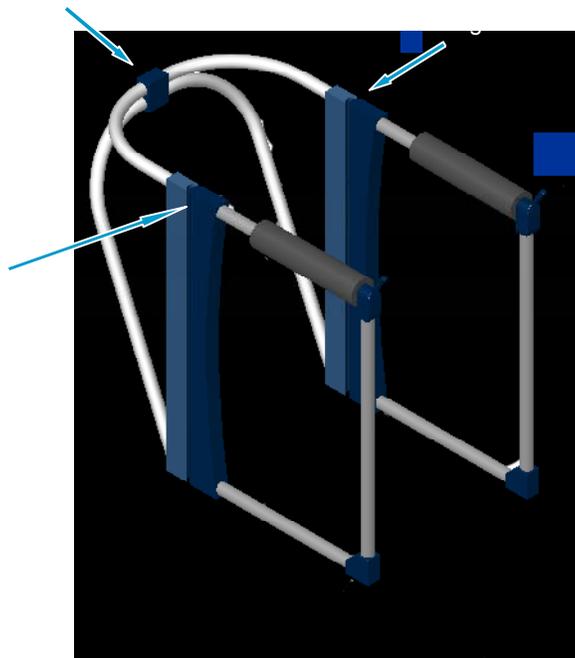
Once the projects were selected, the business and technical teams met so that the former could gain a better understanding of the actual products. The teams then jointly planned the semester's work and established appropriate due dates. Milestones included the traditional components of a business plan such as description of the product, market analysis, financial projections, operations, protection of intellectual property, funding sources, and harvest strategies. The students proceeded with the confidence that bright young people typically bring. They assumed that they would easily meet all deadlines and that the project would go smoothly. This changed when the teams began meeting with potential customers and outside advisors. They quickly discovered that product features needed to change, patent issues loomed, and FDA approval was a major hurdle.

The business issues impacted the technical designs and changes in the technical designs obviously affected the marketing, manufacturing, and financial plans. The students experienced a feedback loop very different than professorial critiques. There were practical constraints and external people challenging their ideas.

Instead of a “straight-line” project with clear milestones, the teams discovered that the planning of a new technical and business venture necessitates much rethinking and rewriting. Customer requests and patent issues affected the design which affected the marketing and manufacturing plans which affected the financial projections. The financial projections in turn affected everything else. In addition, the business teams critiqued the product designs and the technical teams weighed in on the marketing and financial plans. Clear divisions between the business and technical teams became narrower as the semester progressed. The teams worked for almost two months and still felt that they were incomplete. At the end of the Fall term, technical teams presented their project proposals to sponsors and faculty, and business teams presented plans to a group of outside business analysts. Proposed corporate names were: Strider, Biocervical Technologies and Intellisole. A brief description of each follows.

### **Strider**

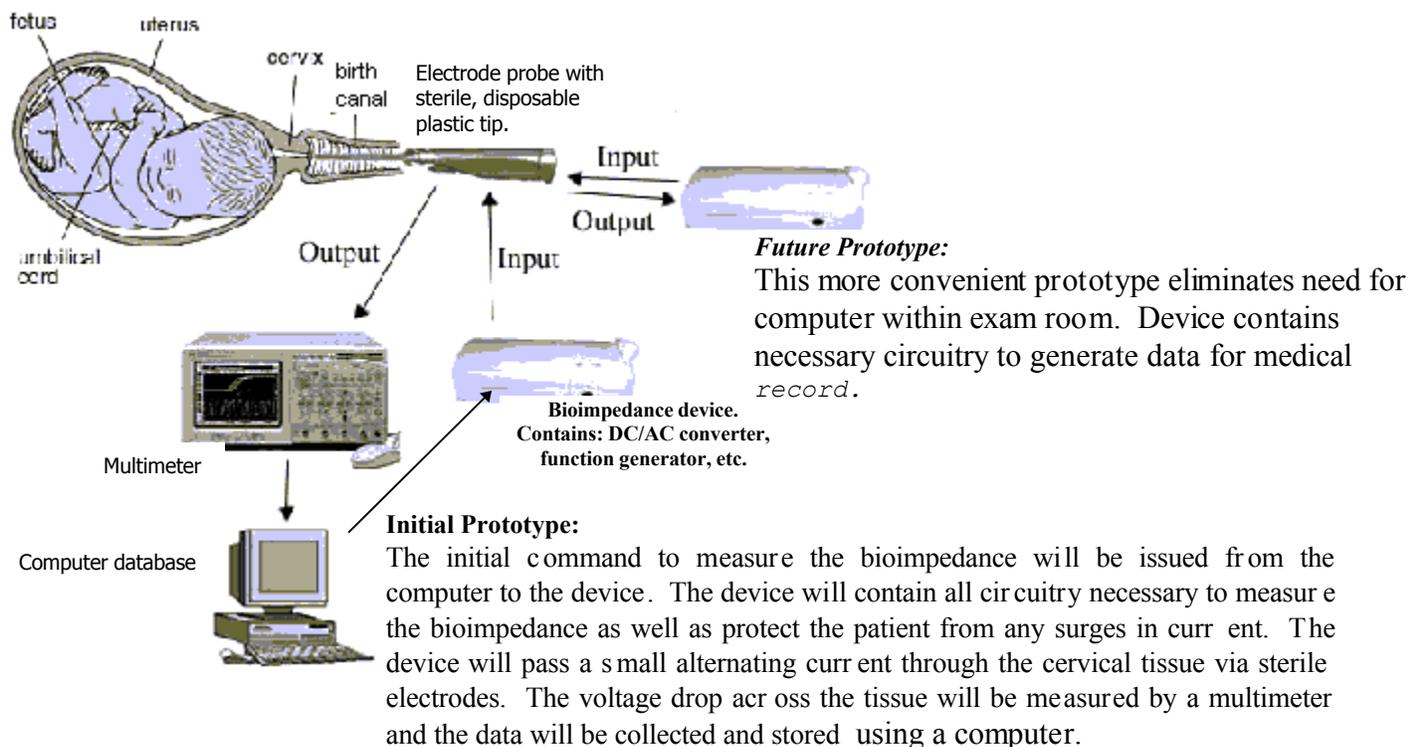
Numbering about 20,000 annually, children with neurological disorders have difficulty walking and need assistive devices to help ambulate and learn proper ambulation. While many pediatric walkers exist, most are miniaturized adult walkers. No walker currently is rehabilitative in nature and none encourage trunk rotation, a key aspect in helping children develop optimal gait. The current concept solution, shown below, is based on a hinged frame technology, where hinges rotate around joints, thereby encouraging the user to use upper body movement while moving forward. A business plan anticipates market penetration through extensive testing with steady state sales of about 5000 units/year and gross revenues between \$2.5M and \$5M annually.



**Figure 1.** An isometric view of Strider concept. Arrows point to rotating hinges, allowing upper body movement while moving forward.

### **Biocervical Technologies**

Despite advances in prenatal care, preterm birth continues to affect 400,000 newborns annually and adds more than \$6B to US health care costs. Current diagnostic tools to prevent preterm birth are ineffective. This project proposes to develop technology, based on measuring cervical impedance, to allow for better detection, and prevention, of premature labor. Since the onset of labor is marked by remodeling of protein, and hence changes in resistance in the cervix, preterm labor can be detected by measuring cervical impedance. The proposed system, shown in Figure 2, allows clinicians to take cervical measurements during routine prenatal exams. The business model involves donating the electronics to clinicians and hospitals and selling the probes, which would number in the millions annually.

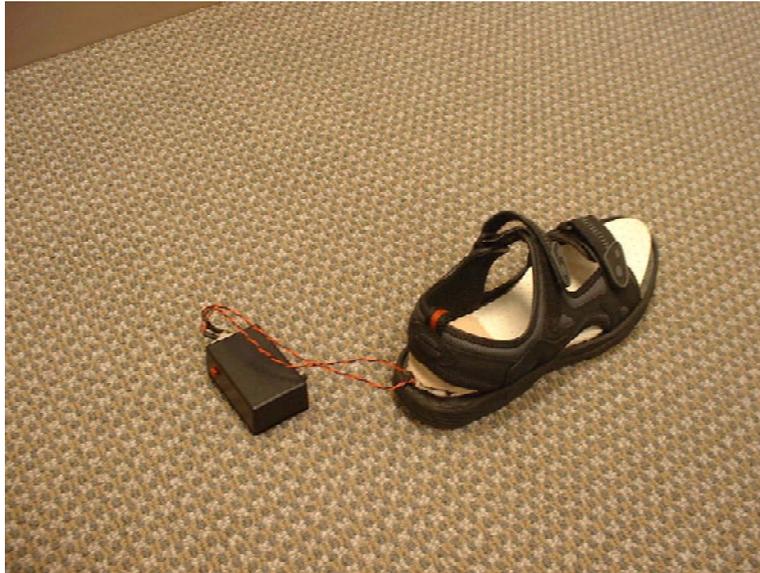


**Figure 2.** Schematic of system to measure cervical impedance.

### **Intellisole**

Patients recovering from lower limb injuries would heal more effectively and more quickly if they could control weight bearing more carefully during their rehabilitation period. Most load measuring systems to facilitate controlled weight bearing are impractical for everyday use and are too expensive to be useful to patients. The proposed foot sensing system, shown in Figure 3, addresses these shortcomings. The sensing system consists of piezoelectric film sensors embedded into a sole or a cast and wired to an RC circuit that would signal when threshold (set

by the therapist or user) is reached. The business model involves a disposal (and hence reimbursable) sensor portion and reusable electronics. Annual sales are expected to be close to 500,000.



**Figure 3.** The foot sensing system. Piezoelectric film within the sole detects changes in load. Circuit in black box processes signal and sends out an alarm when adjustable threshold is exceeded.

#### 4. Perceptions

Although results are limited, integrating the biomedical engineering design program with the entrepreneurship program by having engineering and business students work on the same project appears to hold promise pedagogically. The perceived advantages are as follows:

1. The biomedical projects had much greater appeal to the business students than other project possibilities, such as case studies, joint projects with local businesses, and small student-run businesses.
2. The students organized the projects and managed them through completion. They gained confidence by becoming expert in their products and business plans. They believed that they had identified sources of competitive advantage and were prepared to present and defend their work.
3. Students controlled the work from the beginning, which gave them a sense of ownership. Many business students expressed a desire to continue working on these plans even after the end of the semester.
4. All the students gained experience in working with peers from disparate backgrounds and in negotiating requirements and tasks.
5. The technical and business teams perceived each other as customers. Neither team worked in a vacuum. The technical teams were compelled to address the viability of their products, and the business teams could not make unsubstantiated assumptions. Both teams had to confront reality in the face of challenges by their peers, initial customers, and outside advisors.

6. Better than any case study, the teams learned to balance the allure of an exciting technical innovation with its attendant risks and rewards.

Despite these perceived advantages, more time is needed to fully evaluate the integration of these programs. Certainly, improvements in project selection and project timing can be made. While the technical teams need time to develop their ideas, the business teams like to have a prototype to work with. This issue can be addressed by having technical teams present projects to the Entrepreneurship class in the Spring, at a point when the technical project is further developed than in the Fall. Alternatively, business teams in the Fall Management Accounting class can address projects from the year before, much like they did the foot sensing system.

In addition to changing the term, the business teams are also better formed in the advanced Entrepreneurship course than in Managerial Accounting. Because the Entrepreneurship course carries both marketing and financial prerequisites, it is likely that students will be better able to deal with real customer issues. The more advanced course should also mean that students are better prepared to handle the legal and regulatory issues that arise. It was also clear that we need to make available to students more marketing and legal resources in the future.

## 5. Bibliography

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## 6. Biography

### ROBERT H. ALLEN

Dr. Allen is a Senior Lecturer in Biomedical Engineering at Johns Hopkins University, and has taught and performed research in engineering design for over 15 years. He directs the Design Teams program.

### LAWRENCE ARONHIME

Lawrence Aronhime is a lecturer in the Carey Program at Johns Hopkins University, and has taught accounting and management for over 15 years.

### ARTIN A. SHOUKAS

Dr. Shoukas is a Professor of Biomedical Engineering at Johns Hopkins University, where he has served on the faculty for over 30 years. The recipient of several engineering and medical school teaching awards, Dr. Shoukas envisioned and proposed the Design Teams program within biomedical engineering.

### JOHN C. WIERMAN

Dr. Wierman received a Ph.D. in Mathematics from the University of Washington in 1976. He is a Professor of Mathematical Sciences at The Johns Hopkins University, where he served as Department Chair from 1998 to 2000. During that time he recognized the need and opportunity to found the W. P. Carey Program in Entrepreneurship & Management in 1996, and has since served as its Director.

