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SHARE: Development of Tangible Medical Device Prototypes in a Biomedical Instrumentation Laboratory Course

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This SHARE paper discusses the development of medical device prototypes aimed at addressing various physiological conditions, including Electrocardiography (ECG), Electromyography (EMG), Heart Rate, Photoplethysmography (PPG), and Electrooculography (EOG) measurements. Project-based learning can help close gaps in students' knowledge, from fundamental concepts to hands-on fabrication skills. However, time constraints present a challenge in creating and executing these projects. The project scope and deliverables need to be manageable within the limited time available in the course. Additionally, access to necessary project materials may be limited. It is essential that the components required for prototype fabrication are readily available to complete the tasks. In the Biomedical Instrumentation laboratory course offered at this university, third-year biomedical engineering students work in teams of up to three to design, test, and build biomedical instrumentation that acquires measurements and interprets data from physiological systems. Students gain practical experience with relevant hardware, software, and data collection during the first three quarters of the course. In the final quarter, students select their projects using a white paper proposal approach for approval before starting. The course concludes with a conference-style poster presentation judged by faculty, graduate students, and seniors. The final assessment is a technical report of their project, written in a journal peer-review format to teach students how to prepare a manuscript. Detailed resources for implementing this learning activity, including links to the course syllabus, anonymized student-developed medical device prototypes, and presentation rubrics, are available.

Motivation

Practical, hands-on engineering skills help students develop an engineering mindset and prepare them for the workforce. A survey of personnel in manufacturing, MedTech, and BioTech industries on the core competencies for biomedical engineering (BME) undergraduates indicates that the most desired skills influencing hiring are problem-solving abilities, design experience, and teamwork on projects [1]. Since many engineering courses focus on theoretical fundamentals, laboratory courses help bridge the gap between theory and practical, hands-on knowledge. Specifically, BME lab courses offer advantages by introducing additional learning objectives such as data collection, analysis skills, and the ability to perform and interpret measurements from living systems [2]. These skills help teach BME students professional competencies and prepare them for the workforce. Furthermore, a notable increase in self-efficacy has been observed in BME students engaged in a design-rich undergraduate program [3].

An engineering laboratory course can be taught through various methods, such as a problem-based or project-based approach. Project-based learning offers an advantage because students work on real-world problems that provide relevant experiences, similar to industry practices, helping them develop the skills needed to succeed after graduation [4]. At the University of South Florida, students in a third-year, two-credit, project-based laboratory course design, build, and test a medical device prototype during the last quarter of a 16-week program. Prior to this course, students have completed a foundational lab on design principles and are enrolled in a co-requisite ethics course covering FDA approvals. Essential principles like design for manufacturing and assembly (DFMA) and benchmarking are taught in the two-semester senior design course.

Learning Objectives

The objective of the project activity is to equip students with the skills to measure and analyze biological signals from physiological systems through hands-on experience. Students learn about biomedical Instrumentation Design, Data Acquisition, Signal Processing, and Physiological Systems and Measurements, including cardiovascular, respiratory, nervous, and muscular systems. This project covers some of ABET student learning outcomes in Applying Knowledge, Design Competence, Communication, Teamwork, and Experimental Skills.

Implementation

The biomedical teaching laboratory at the University of South Florida is equipped with various bio-amplifiers, physiological toolkits, microcontrollers, and electrical components. The lab is funded by student course fees. By the eighth week of the course, the instructor introduces student teams of three to project areas such as Heart rate monitor, Blood, Respiratory, and/or Gas flow measurements, Joint Flex Sensor, Galvanic Skin Response electrodes, Neuroamplifier, PPG, ECG, EMG, EOG, and EOG Amplifiers. The project requirements involve selecting a specific disease state and designing a monitoring device to collect biological data, which may or may not include informing the user or a physician. All designs must incorporate programming concepts, a microcontroller, circuit design, bio-signal processing, Spice simulation (optional), and a novel component if using previously published work.

Student teams choose their own projects and are not limited to the given project areas; however, all projects must submit a one-page white paper proposal for approval. The proposal must include the Problem Statement, Instrumentation Design, Project Plan, Summary of the approach or strategy to solve the problem, Bill of Materials, Proposed Timeline, and References. The instructor and teaching assistant review each proposal for feasibility and material availability before approval. By the twelfth week of classes, each team receives a package with their project materials and a list of faculty, labs, and campus facilities available to support their project. Since this is a guided-design team project [5], each team is assigned a weekly project status meeting with the instructor and teaching assistant to help steer the project to completion.

During the project phase, all previously mandatory assessments are discontinued. There are no quizzes, prelabs, or post-labs during project weeks; however, student teams are required to work on their projects in the lab. At the fourteen-week mark, students receive poster presentation guidelines to showcase their design in a standard poster format. All teams present their work on the same table, where faculty, staff, students, and their families or friends are invited to watch. Faculty, graduate students, and BME seniors serve as judges. The final assessment is a manuscript in the format of a published journal article.

Detailed resources for implementing this project design activity, including access to the project information, an actual list of student project titles, anonymized student-developed medical device prototypes, the white paper evaluation sheet, and the poster presentation rubric, are attached in the appendix. Lecture materials are available on request.

Situational Factors

In the first twelve weeks of the course, students learn about noise filtering, signal amplification, PCB design, microcontroller programming, temperature transducers, building a bio-amplifier system, obtaining data from human and animal physiological systems, and data acquisition and processing skills. This knowledge is designed to help students complete their projects; however, the challenges they face often reveal gaps in their understanding of certain concepts or help them master specific component usage. Without a solid foundation, students may struggle to complete their projects. It is recommended to start project scoping and set a material ordering deadline well before the twelfth week of classes.

The funding model for projects has been revised numerous times. It has ranged from providing students with a limited budget to restricting the types of components they can use. With a large student enrollment, this process can become cumbersome. It's best to start project scoping as early in the semester as possible to minimize the risk of delayed material shipments. Additionally, helping students understand their circuit design through simulations early on is crucial, and knowing how to pivot to alternative approaches if needed is recommended. Students often fixate on their original design and get stuck if they are unable to measure the intended outputs.

This study did not meet the regulatory definition of human subjects research and therefore did not require Institutional Review Board (IRB) approval per the University of South Florida guidelines.

References

[1] J. A. White et al., "Core Competencies for Undergraduates in Bioengineering and Biomedical Engineering: Findings, Consequences, and Recommendations," Annals of Biomedical Engineering, vol. 48, no. 3, pp. 905-912, 2020/03/01 2020, doi: 10.1007/s10439-020-02468-2.

[2] R. A. Linsenmeier and A. Saterbak, "Fifty Years of Biomedical Engineering Undergraduate Education," Annals of Biomedical Engineering, vol. 48, no. 6, pp. 1590-1615, 2020/06/01 2020, doi: 10.1007/s10439-020-02494-0.

[3] S. Higbee, D. Harrell, A. Chase, and S. Miller, "A Study of Biomedical Engineering Student Self-efficacy toward Design throughout an Undergraduate BME Curriculum," Biomedical Engineering Education, vol. 5, no. 1, pp. 15-36, 2025/01/01 2025, doi: 10.1007/s43683-024-00163-5.

[4] S. Senay, "On the Impacts of Project-based Learning for Workplace Preparedness of Engineering Graduates,"10th System of Systems Engineering Conference (SoSE), 17-20 May 2015, pp. 364-367, doi: 10.1109/SYSOSE.2015.7151921.

[5] A. J. Nimunkar, J. P. Puccinelli, M. S. Bollom, and W. J. Tompkins, "Using Guided Design Instruction to Motivate BME Sophomore Students to Learn Multidisciplinary Engineering Skills," ASEE Annual Conference & Exposition, 2014, pp. 24.1331.

APPENDIX: Project Information, Sample Design Prototypes, Project Title, and Rubrics

- **Electronics kit**
  Available for purchase at: https://www.sparkfun.com. Students may bring the supply kit to every Lab session.

- **Software**
  All software licenses are accessible on the BME teaching Lab computers, like those in the DFX Lab, and some licenses can also be used on your personal computer. The software includes LTspice, Spiker Recorder, Arduino IDE, LabScribe, MATLAB, and the Microsoft Office Suite.

Course Topics and Schedule

Week	Lab Experiments	Lecture Materials
1/Lab 0	Fundamentals of Oscilloscopes	Lab Orientation and Safety training
2/Lab 1	Circuit Design & Measurement (RC, RL, Low/high pass filters)	Fundamental Circuits and Filtering
3/Lab 2	Amplifier Circuit	AC Amplification and Signals (ADC, Time, Sampling, Noise)
4/Lab 3	Microcontroller	System Modeling & Design and Statistics
5/Lab 4	Temperature Measurement	Transducers, Wheatstone bridge
6/Lab 5	Spectrophotometry	Spectrophotometry System
7	**Exam #1 (Bench + Written)** Recitations hours TBD	
8/Lab 6	Animal Nerve Conduction	Neural Circuits and Action Potential **Project Selection**
9/Lab 7	Electromyogram (EMG) Signal	Skeletal Muscle Electrical Activity
10	**Spring Break**	
11/Lab 8	Electrocardiography (ECG) Signal	Heart Sounds and Electrocardiography
12/Lab 9	Heart sounds and Blood pressure Cardiac Output and Pulse Plethysmography (PPG)	Project Assignment One-page Proposal due
13/Lab 10	Guided Project	**Exam #2 (Written)**
14/Lab 10	Guided Project	Guidelines for Poster Presentation
15/Lab 10	Guided Project	
16/Lab 10	**Poster Presentations, Hardware & Protocol Submissions**	

Guided Project: Individual groups will select a topic from a list of provided projects. Students are required to design, build, and test instrumentation capable of obtaining relevant physiological data. Students are required to attend lab sessions during the project weeks and other times as needed. Deliverables will include the submission of the hardware, a written technical protocol, and a poster presentation. The format for the technical protocol and poster presentation will be discussed in class and posted on Canvas.

Sample Design Prototypes

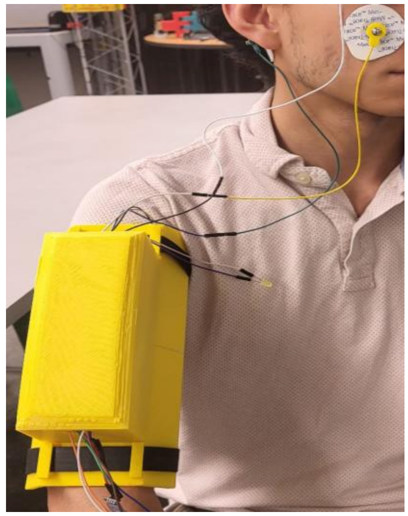

Figure A1: Wireless EOG-Based
blinking detection device

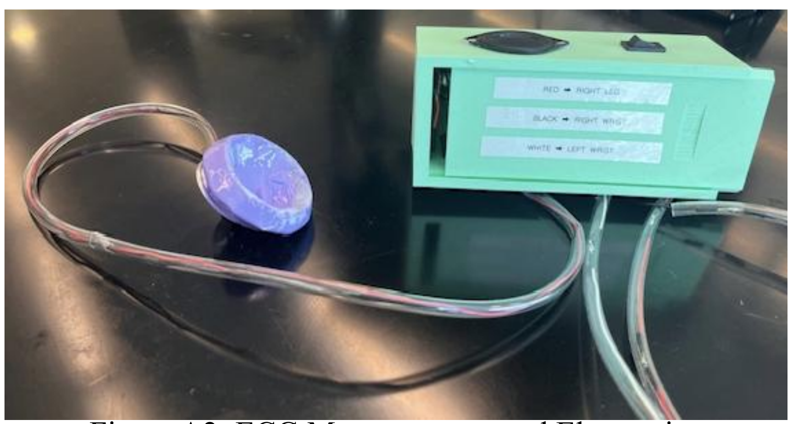

Figure A2: ECG Measurements and Electronic
Stethoscope

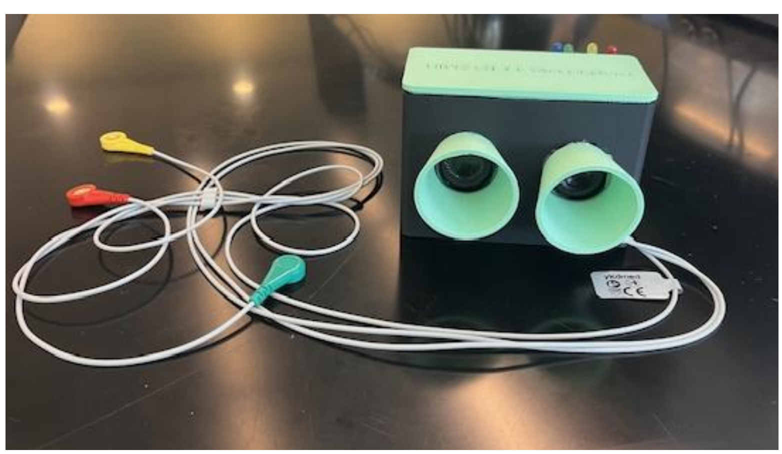

Figure A3: ECG-Based Emotion Detector and Regulator

Student Group Project Titles

1. English to ASL Translation using Auditory Processing
2. Wearable Muscle Activity and Heart Rate Monitor for Seizure Tracking in Epilepsy Patients
3. Fatigue Watch: Measuring Fatigue through EMG Signals
4. Portable Arduino-Based EMG Detection System for Drowsiness in Drivers
5. ECG-Based Emotion Detector and Regulator for Individuals with Down Syndrome
6. Detection of Heart Sounds and Blood Flow Rate Through Phonocardiogram and PPG
7. A Dual Approach to Stress Detection and Monitoring using PPG and GSR
8. REM State Detection through EOG Analysis
9. Wireless EOG-Based Blinking Detection Device for Driver Drowsiness Monitoring
10. Artificial Homeostasis of Blood Pressure Bluetooth Hardware
11. PPG Heart Rate Monitoring for Exercise Tracking
12. Integrating EKG Measurement and Electronic Stethoscope for Telemedicine Purposes
13. Artificial Homeostasis of Heart Rate using PPG
14. Flexible Dry Electrodes Used to Gage EMG to Grip Strength

White Paper Proposal Evaluation

Criteria	Score (points)
Logical Problem Statement	0.2
Instrumentation Design and Project Plan: Summary of the Project Approach Includes the Proposed Circuit Design Provides a strategy on how to solve the problem	1.0
Includes an itemized list of materials and the Bill of Materials.	0.4
The paper includes logically anticipated results	0.2
The paper includes a logical proposed timeline	0.2

Poster Presentation-Evaluation Sheet

Poster # or Title:

Presenters: (1) __________ (2)__________ (3) _____________

Date: __________ Course:__________ Evaluator:

	3 - Expert	2 - Practitioner	1 - Apprentice	0 – Novice
Poster Mechanics Score:	• The poster is exceptionally attractive in terms of design, layout, and neatness. • Graphics are easily viewed and are related to the topic, making the material easier to understand. • No grammatical mistakes on the poster.	• The poster is acceptably attractive. • Most graphics are easily viewed and relate to the topic. • There is one grammatical mistake on the poster.	• The poster is a bit messy. • Many graphics are not clear or are too small. • There are two grammatical mistakes.	• The poster is distractingly messy or very poorly designed. It is not attractive. • Graphics do not relate to the topic. • There are more than two grammatical mistakes on the poster.
Technical Details Score:_______	• High level of relevant detail is presented to allow the audience to make judgments about the content.	• Sufficient technical detail is included to enable the audience to understand the nature of progress.	• In places, the information was too detailed or was lacking.	• Significant amounts of technical detail are lacking or inadequate so that the audience cannot appreciate the progress that has been made.
Hardware/ Simulation Score:	• demonstrates proficiency and complete integration of engineering technology used. • Prototype is fully functional.	• reflects minor deficiencies and limited integration of engineering technology. • Partially functional with a minor flaw.	• reflects minor deficiencies and the integration of engineering technology has major limitations. • Somewhat functional with major flaws.	• reflects major deficiencies and the integration of engineering technology has major limitations. • Prototype is not functional.
Data, Results & Discussion Score:	• Presentation includes thorough description of empirical results and explains the importance of the results.	• Presentation includes sufficient results to draw conclusions.	• Presentation does not include enough results to draw conclusions.	• Conclusions are vague or unrelated.
Presentation Level Presenters 1. Score: 2. Score: 3. Score:	• The audience's interests are piqued and well considered. • The audience's attention has been drawn and engaged.	• The audience's knowledge level and interests have been considered. • The audience's attention has been maintained.	• Some opportunities for adjusting the presentation level for the audience have been missed. • The audience's attention is weak.	• The knowledge level of the audience has not been considered. • The audience is not paying attention.
Handling of Questions Presenters 1. Score: 2. Score: 3. Score:	• Presenters demonstrate full knowledge of the material and can explain and elaborate on expected questions.	• Presenters have sufficient knowledge of the material to answer expected questions.	• Presenters have difficulty answering expected questions beyond a rudimentary level.	• Presenters cannot answer expected questions.

Comments (use the back page if necessary):