AC 2011-1920: COMPREHENSIVE TEACHING OF MEDICAL DEVICES

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Introduction

Many undergraduate bioengineering programs state on their websites that they are training their graduates to enter the medical device industry. However, most curricula contain little direct medical device content. When medical devices are discussed, the devices are electrical devices, which are taught within the context of a bioinstrumentation course. The bioinstrumentation textbook used may not provide up-to-date information on basic medical devices such as pacemakers, mechanical ventilators, and hemodialysis delivery systems. Mechanical medical devices such as tissue heart valves are often not discussed in other courses.

A semester course was developed which addresses these issues, with lectures summarized as a textbook that will be published by Elsevier Academic Press in late 2011. The textbook Author has significant medical device industry experience, and wrote the book to prepare undergraduate bioengineering students to enter the medical device industry. The purpose of this study is to examine if this goal was met through an industry survey and textbook comparison.

Textbook

Medical Device Technologies: A System-Based Overview Using Engineering Standards [1] is divided into two Parts. In Part I, foundational medical device topics, such as some common sensors of medical instruments, are described in chapter 1. Students are then exposed to 19 basic medical devices in 19 chapters: the electrocardiograph, pacemaker, external defibrillator, implantable cardioverter defibrillator (ICD), heart valve, blood pressure monitor, catheter/bare metal stent, hemodialysis delivery system, mechanical ventilator, pulse oximeter, thermometer, electroencephalograph, deep brain stimulator, cochlear implant, functional electrical stimulator, intraocular lens implant, hip prosthesis, drug-eluting stent, and artificial pancreas. The medical devices chosen include Nobel Prize and Lasker Clinical Medical Research Award winners, vital signs devices, and devices in high industry growth areas. Imaging devices are excluded because they are often covered in a separate imaging course.

Each device chapter includes discussion of appropriate physiology, clinical need, historical devices, a system description with system diagram, and five requirements from applicable engineering standards. For example, the electrocardiograph chapter describes five requirements from three Association for the Advancement of Medical Instrumentation (AAMI) standards:

1. ANSI/AAMI EC11:2007 Diagnostic electrocardiographic devices: input dynamic range.
2. ANSI/AAMI EC11:2007 Diagnostic electrocardiographic devices: frequency response.
3. ANSI/AAMI EC11:2007 Diagnostic electrocardiographic devices: system noise. [2]
4. ANSI/AAMI EC57:2003 Diagnostic electrocardiographic devices: arrhythmia detection.[3]
5. ANSI/AAMI EC13:2002 Cardiac monitors, heart rate meters, and alarms: leads off detection. [4]

In three chapters, a case study summarizing a notable Food and Drug Administration (FDA) recall of the discussed device is highlighted. Each of these recalls significantly affected the medical device industry. Exercises at the end of each chapter include four questions related to an assigned reading of the primary literature. While students could submit answers to these four questions as part of traditional homework assignments, it is recommended that these questions spur an oral discussion during lecture.

The systems approach is powerful because it enables students to quickly identify relationships between devices, after they learn specifics about system components. For example, the basic digital instrument and external electrical stimulator system diagrams are shown in Figures 1 and 2. Students understand how an Automated External Defibrillator (AED, Figure 3) is a combination of a digital instrument and external electrical stimulator.

In Part II of the textbook, practical lab experiments for students are described. To gain experience with real equipment, the experiments include a pacemaker lab, echocardiography lab, and patient monitoring lab. For example, students use a St. Jude Medical pacemaker and programmer to identify the capture threshold in a simulated patient. In this patient and two others, they also identify the patient's arrhythmia and observe how pacemaker therapy affects each patient. In consideration of equipment costs, other labs use low-cost and academic equipment. These labs are the electrocardiograph design lab, electrocardiograph filtering lab, thermometry accuracy lab, surface characterization lab, and entrepreneurship lab.

Curriculum Implementation Example

Within the curriculum of Keck Graduate Institute's (KGI) Professional Science Masters program, these textbook topics are taught in a medical device survey course. The majority of KGI graduate students have science, rather than engineering B.S. degrees, so engineering math that appears in the textbook is not covered. This survey course and two half-courses in medical device regulation and market release provide students with the necessary background for obtaining medical device industry positions such as regulatory affairs specialist and clinical research associate.

Initially, the students do not value learning about medical devices as systems, but they realize the power of the systems approach over time. Before the first course, they had barely touched any medical device; now, in their third course, they can conceptually mitigate failure modes in devices such as an ICD. In the textbook Author's latest three semester cycle (Spring 09, Fall 09, Spring 10), she received the following student evaluation (course/instructor) mean scores on a 5 point scale: 3.94/4.11, 4.49/4.67, 4.57/4.85, respectively.

Methods

In order to better understand medical device industry hiring needs, a survey was created and sent (SurveyMonkey, Palo Alto, CA) via e-mail to 12 senior medical device industry engineers. These engineers were ask to rank specific skills knowledge and concept knowledge categories in terms of importance: 0 = Not important, 1 = Somewhat not important, 2 = Neutral,

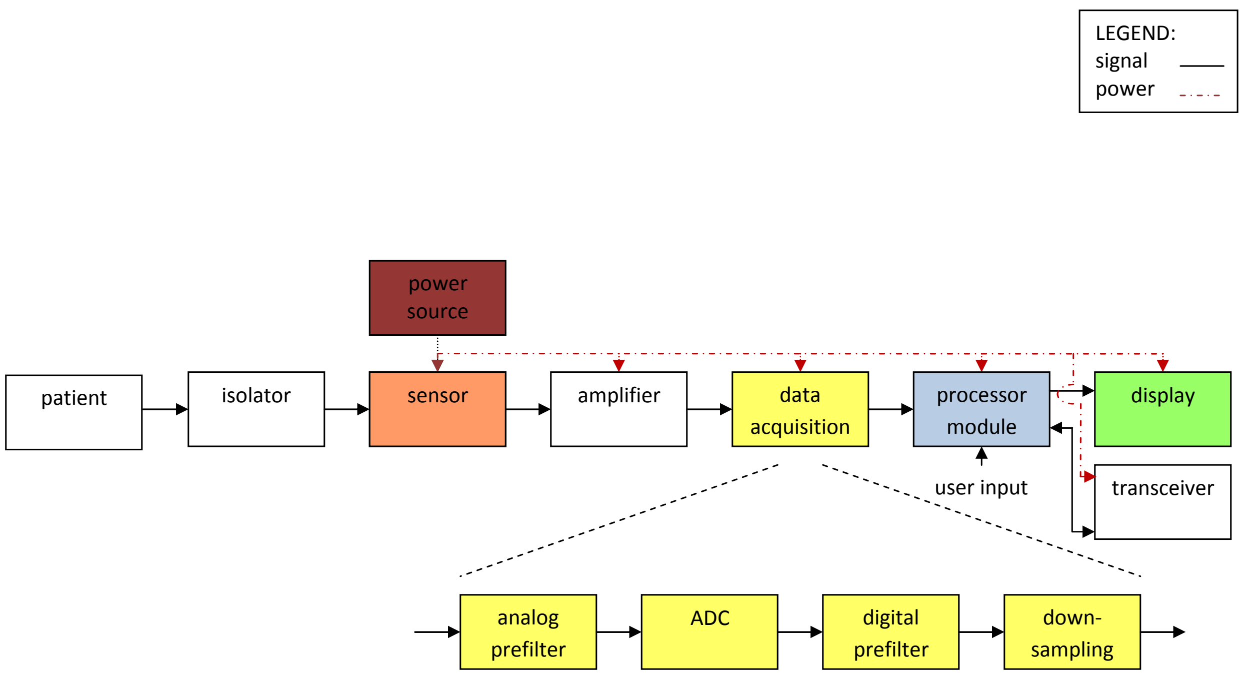

Figure 1. Digital instrument system diagram. ADC = analog-to-digital conversion. The order of the isolator and sensor may be reversed, depending on the digital instrument. For example, in an oral electronic thermometer, the probe cover precedes the thermistor. In an electrocardiograph, the surface electrodes precede the isolation transformer.

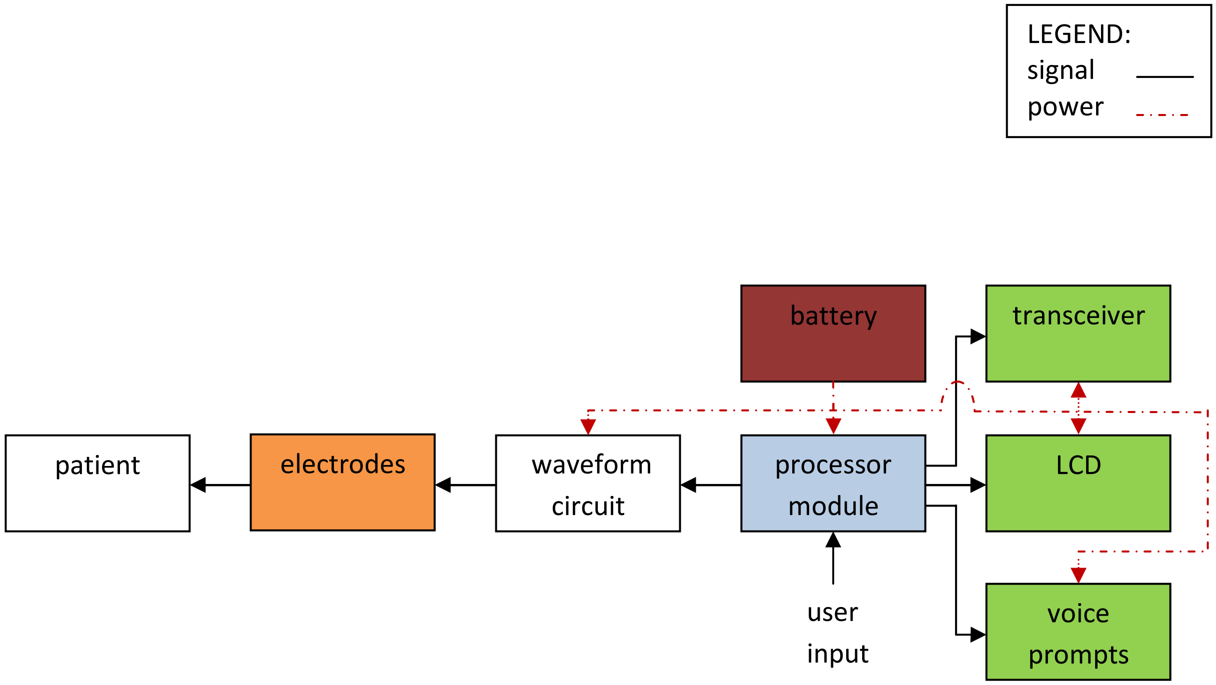

Figure 2. External electrical stimulator system diagram. LCD = liquid crystal display.

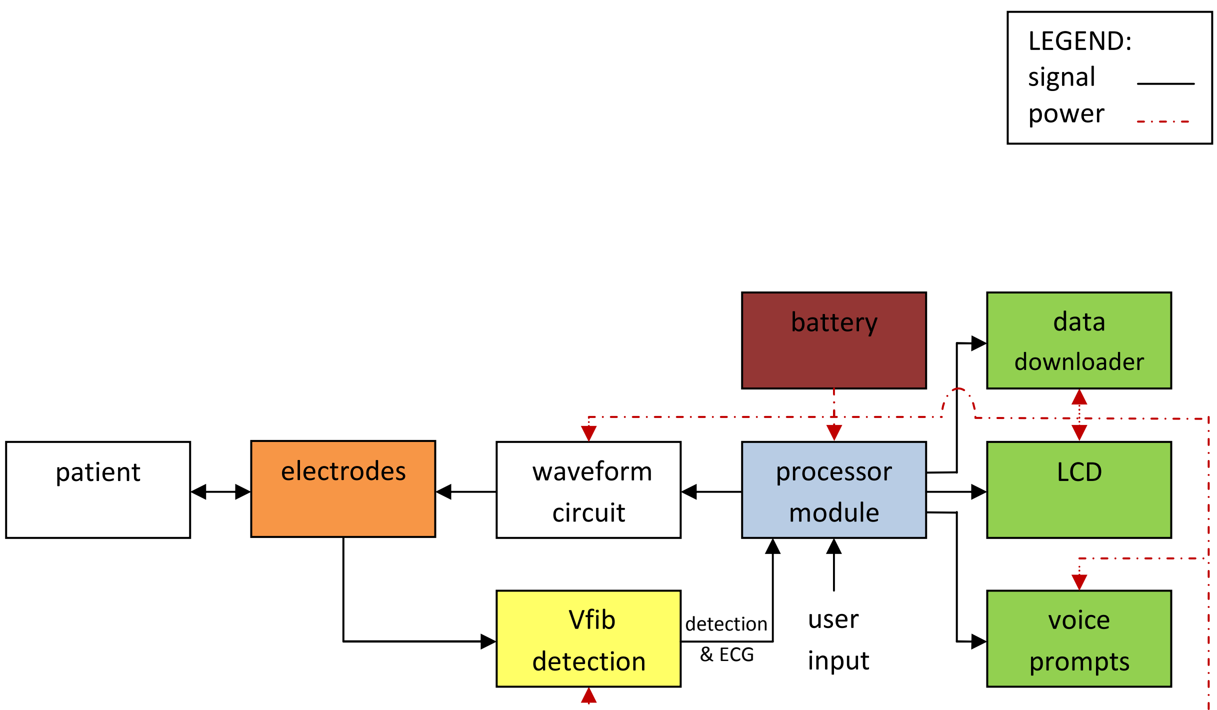

Figure 3. Automated External Defibrillator (AED) system diagram. LCD = liquid crystal display; Vfib = ventricular fibrillation.

3 = Somewhat important, 4 = Very important. The skills knowledge categories were obtained from a review of recent engineering society surveys and conference proceedings. The engineering societies considered were Biomedical Engineering Society (BMES), International Electrical and Electronic Engineering Society (IEEE), and American Society of Mechanical Engineers (ASME). Additional skills knowledge and concept knowledge categories were chosen by the Authors.

The categories receiving combined survey scores ≥ 50% for rankings 3 and 4 were given to two survey coders. Each was asked to determine if the categories appeared in *Medical Device Technologies* and edition 4 of Webster's *Medical Instrumentation*. Edition 3 of *Medical Instrumentation* was the most widely adopted bioinstrumentation textbook in 2005. [5] This textbook comparison was suggested by an ASEE conference reviewer. Book appearance codes were: 0 = Not present (can't find), 1 = Somewhat not present (very little detail), 2 = Present, 3 = Very present (book chapter, recurring book section). Coding concordance was assessed using Cohen's Kappa test. [6]

Results

Survey Construction

Through a Google search, three recent engineering education engineering initiatives were identified and investigated. The BME Council of Chairs held an educational workshop in concert with the 2010 BMES annual meeting. While the workshop description stated that industry representatives would participate, no industry presentations were given. [7] IEEE and IBM jointly hosted a four day summit on Transforming Engineering Education in Ireland in 2010. In the summary of the summit proceedings, a follow-on activity listed by the program chair was to develop "a concrete list of 'desired but missing' skills, mostly by industry" by Spring, 2011. [8] In their Vision 2030 project, the ASME Center for Engineering Task Force was asked to "define the knowledge, skills and abilities that mechanical engineering and mechanical engineering technology graduates should have to be globally competitive in the 21st century". A draft of the Vision 2030 report, which includes the results of an industrial survey, was published in 2010. [9]

ASME sent a web-based survey in Spring, 2010 to its industrial members. The response rate was not given; 610 members responded. About half of respondents (47%) had engineering positions. Respondents also included project managers (18%), chief engineers (14%), and directors (7%). Slightly more than half were involved with mechanical engineer (ME) hiring; about half directly supervised mechanical engineers. The respondents were asked to assess recent B.S. ME graduates according to 15 skills knowledge categories that were culled from an earlier survey. Six categories were assessed with highest assessment percentages of "Weak". These categories were practical experience, oral/written communication, overall systems perspective, engineering codes and standards, project management, and business processes. [9] These categories were used as skills knowledge categories in the medical device industry survey.

Vital signs medical devices, appropriate physiology, and biocompatibility were added as skills knowledge categories. These additions reflect the ABET bioengineering program criteria topics of "measurements on and interpret data from living systems", "physiology", and "interaction between living and non-living materials and systems".[10]

Twenty-one concept knowledge categories were chosen for the survey. These categories were: artificial pancreas, cardiac catheterization system, (coronary) bare metal stent, blood pressure monitor, cochlear implant, deep brain stimulator, drug-eluting stent, electrocardiograph, electroencephalograph, external defibrillator, functional electrical stimulator, heart valve, hemodialysis delivery system, hip prosthesis, implantable cardioverter defibrillator, intraocular lens implant, mechanical ventilator, pacemaker, pulse oximeter, thermometer, vascular graft.

The survey began with general questions, such as number of years worked in the medical device industry, if engineering training had an electrical emphasis, if current work is on electrical medical devices, and involvement in hiring engineers. A valid respondent was required to answer positively to either engineering training with an electrical emphasis or current work on electrical medical devices. Respondents were asked to "indicate the importance of the following candidate skills/concept knowledge when hiring a new B.S. engineering graduate for the medical device industry in general, but NOT specifically for your company." Respondents were able to provide open-ended comments throughout the survey.

Survey Results

The survey response rate was 75% (9/12 respondents), and required several requests for survey completion. The respondents worked in the medical device industry an average of 24 years. All were trained in electrical engineering or biomedical engineering with an electrical emphasis. All work on electrical medical devices, and are involved in hiring engineers. The job titles of these respondents were:

- Chief Scientist/Founder
- Director, Advanced Research
- Director, R&D (2 respondents)
- Director of Research
- Manager Director (medical device industry support services)
- Research Fellow
- Sr. Principal Engineer
- Vice President, Product Development

Out of 30 candidate categories, 14 candidate categories were rated as somewhat important or very important by over 50% of the respondents. These candidate categories are listed in Table 1. Concept knowledge categories that were rated as somewhat important or very important by 44% of respondents were cardiac catherization, hemodialysis delivery systems, ICD, and pacemaker.

Out of 9 skills knowledge categories, respondents chose all 6 categories suggested by the results of an ASME industry survey. Of the remaining 3 categories suggested by ABET bioengineering program criteria, respondents chose two: vital signs medical devices and appropriate physiology.

The skills knowledge category biocompatibility was ranked neutral in importance. Optional

Table 1. Significant candidate categories, as determined by an internet survey. % Respondents refers to those respondents who rated category as 3 - Somewhat important or 4 = Very important. Two survey coders then observed if these categories were present in two books. The codes were: 0 = Not Present, 1 = Somewhat not present, 2 = Present, 3 = Very present. The averaged codes are given.

Knowledge Type	Significant Candidate Category	% Respondents	Averaged Code *Medical Instrumentation*	Averaged Code *Medical Device Technologies*
Skill	Practical experience	78%	1	3
	Oral and written communication	100%	1.5	2.5
	Overall systems perspective	78%	2	3
	Engineering standards	56%	1	3
	Business practices	89%	1	2.5
	Project management	78%	0	0
	Vital signs medical devices	78%	1.5	2
	Appropriate physiology	56%	3	3
Concept	Blood pressure monitor	67%	3	3
	Electrocardiograph	67%	2	3
	Electroencephalograph	56%	2	3
	External defibrillator	56%	1	3
	Pulse oximeter	56%	1	3
	Thermometer	56%	1	3

comments for biocompatibility included “you can look that up” and “perhaps more appropriate with a person with an advanced degree”. Other open-ended responses to the request for other practical skills included good work habits, hospital experience (at least 2 observation trips or hospital internship), and enthusiasm for working in the health care industry.

Out of 21 concept knowledge categories, respondents chose 6 categories. These categories are all noninvasive medical devices: blood pressure monitor, electrocardiograph, electroencephalograph, external defibrillator, pulse oximeter, and thermometer. Except for the external defibrillator, the other devices are primarily medical instruments that measure patient energy. Most concept knowledge categories were ranked neutral in importance. Optional comments for this section included the following:

- “They should know one device, but which one is not important.”
- “A B.S. degree is probably not deep enough to specialize in one area.”
- “These questions would indicate that an engineer might be hired within a specific industry sector, so, I would not imagine a breadth at the BS level of these categories is likely.”

Textbook Comparison

Two survey coders searched for these 14 categories in the two textbooks. Their averaged codes are given in Table 1. The sum of averaged codes for *Medical Instrumentation* and *Medical*

Device Technologies were 21 and 37, respectively. The maximum possible sum was 42. Cohen's Kappa for the original codes was calculated as 0.79, which demonstrates good strength of agreement.

Neither of the textbooks discusses project management. The other 7 skill knowledge categories are present or very present in *Medical Device Technologies*. In contrast, the other 7 skill knowledge categories are somewhat not present to very present in *Medical Instrumentation*.

All 6 concept knowledge categories are very present in *Medical Device Technologies*. These categories are somewhat not present to very present in *Medical Instrumentation*.

Discussion

Medical device industry survey respondents chose all 6 skills knowledge categories suggested by ASME industry survey respondents. This reinforces industry's need for B.S. engineers with practical experience, oral and written communication, overall systems perspective, engineering standards, business practices, and project management. Their choices of vital signs medical devices, appropriate physiology, and 6/24 medical devices, along with open-ended comments, suggest that an understanding of how medical device components fit together as various device systems is more important than deep knowledge of a specific medical device.

No one textbook can incorporate all categories that industry desires in new B.S. graduates. Based on survey and survey coder results, *Medical Device Technologies* addresses more categories, in greater depth, than does *Medical Instrumentation*. The consistent systems approach taken by *Medical Device Technologies* may be a better match for industry needs.

Only 9/12 engineers completed in this survey after several requests for participation. In preparation for the ASEE presentation, the Authors will continue to solicit participation from more industry engineers. It was surprising that no implantable devices were chosen by the majority of respondents. With a larger sample size such as n=20, industry hiring needs may become clearer.

Conclusion

This study provides evidence that *Medical Device Technologies* prepares undergraduate bioengineering students to enter the medical device industry. This textbook provides coverage of major industry needs, such as practical experience, oral and written communication, overall systems perspective, engineering standards, and business practices. The textbook uses a consistent systems approach to expose students to medical device components and various device systems that utilize these components.

Acknowledgment

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