# Course Change Proposal
## Form A

<table>
<thead>
<tr>
<th>Academic Group (College): ECS</th>
<th>Academic Organization (Department): EEE</th>
<th>Date: 2/7/08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Course Proposal:</td>
<td>Department Chair: Suresh Vadhva</td>
<td>Submitted by: John Oldenburg</td>
</tr>
<tr>
<td>New <em>x</em> Change ___ Deletion ___</td>
<td>For Catalog Copy: Yes <em>x</em> No ___</td>
<td>Semester Effective:</td>
</tr>
<tr>
<td>Does this course fulfill a requirement for single-subject or multiple subject credential students? Yes ___ No <em>x</em></td>
<td>CCE (Extension): Yes ___ No ___</td>
<td>Fall ___ Spring <em>x</em>, 2009 ___</td>
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This course replaces experimental course Subject Area (prefix) and Catalog Nbr (course number):

## Change from:

<table>
<thead>
<tr>
<th>Subject Area (prefix) &amp; Catalog Nbr (course no.):</th>
<th>Title:</th>
<th>Units:</th>
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## Change to:

<table>
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<tr>
<th>Subject Area (prefix) &amp; Catalog Nbr (course no.):</th>
<th>Title: Design of Devices &amp; Systems for Market Application</th>
<th>Units: 3</th>
</tr>
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## JUSTIFICATION:

This course is a course in an elective sequence on instrumentation design, with particular emphasis on the market requirements for biomedical instrumentation. It is particularly important for engineering designers to understand the industrial process of design and development for market applications, and the standards, testing, certification, and regulation which govern the marketplace.

## NEW COURSE DESCRIPTION:
(Not to exceed 80 words, and language should conform to catalog copy. See http://www.csus.edu/acad/uniymanual/crspsl.htm - Guidelines for Catalog Course Description)

This course considers the key issues involved in the industrial design process, exactly as they would arise in real world device applications. The emphasis of the course is on the process for medical device applications, but that process is very similar for other market applications. Coverage includes analysis of product from conception through to delivery using actual industry examples. Topics include materials selection, safety, prototyping, pre-market testing, validation, liability, and learning from failure.

## Note:

Prerequisite: EEE 120, EEE 122, or instructor permission

Enforced at Registration: Yes ___ No _x_

Corequisite:

Enforced at Registration: Yes ___ No ___

## CAN (California Articulation Number):

<table>
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<tr>
<th>Graded: Letter <em>x</em> Credit/No Credit ___</th>
<th>Instructor Approval Required? Yes ___ No <em>x</em></th>
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</thead>
</table>

## Course Classification (e.g., lecture, lab, seminar, discussion):

Course Classification: C4

Title for CMS (not more than 30 characters):

Design of Devices and Systems

Cross Listed?

Yes ___ No _x_

If yes, do they meet together and fulfill the same requirement, and what is the other course.

How Many Times Can This Course be Taken for Credit? _1_

Can the course be taken for Credit more than once during the same term? Yes ___ No ___
FOR NEW COURSE PROPOSALS OR SUBSTANTIVE CHANGES ONLY:

**Description of the Expected Learning Outcomes:** Describe outcomes using the following format: “Students will be able to: 1), 2), etc.” See the example at http://www.csus.edu/acaf/example.htm

Upon completion of this course the student will be able to:

1. Confidently engage in the process of device and system design for specific market application.
2. Engage in best-practice industrial design and understand the engineering tools commonly employed in the process.
3. Carry out necessary pre-market testing, prototyping and validation.
4. Document the design process and the certify compliance of products with applicable standards and regulations.
5. Avoid common mistakes and pit falls in the process of product development

**Attach a list of the required/recommended course readings and activities [Note: it is understood that these are updated and modified as needed by the instructor(s).] This attachment should be forwarded only to your Dean's office, not Academic Affairs.**

**Assessment Strategies:** A description of the assessment strategies (e.g., portfolios, examinations, performances, pre-and post-tests, conferences with students, student papers) which will be used by the instructor to determine the extent to which students have achieved the learning outcomes noted above:

- Homework assignments with problems incorporating practical design requirements and realistic constraints.
- Exams
- Device design project report

**For whom is this course being developed?**

<table>
<thead>
<tr>
<th>Majors in the Dept</th>
<th>Majors of other Depts</th>
<th>Minors in the Dept</th>
<th>General Education</th>
<th>Other</th>
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<tr>
<td>x</td>
<td></td>
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Is this course required in a degree program (major, minor, graduate degree, certificate)? Yes ______ No ______

If yes, identify program(s):

Does the proposed change or addition cause a significant increase in the use of College or University resources (lab room, computer facilities, faculty, etc.)? Yes ______ No ______

If yes, attach a description of resources needed and verify that resources are available.

Indicate which department or programs will be affected by the proposed course (if any). None

The Department Chair's signature below indicates that affected programs have been sent a copy of this proposal form.

**Approvals:** If proposed change, new course or deletion is approved, sign and date below. If not approved, forward without signing to the next reviewing authority, and attach an explanatory memorandum to the original copy.

**Signatures:**

<table>
<thead>
<tr>
<th></th>
<th>Date</th>
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<tbody>
<tr>
<td>Department Chair:</td>
<td>3/27/2008</td>
</tr>
<tr>
<td>College Dean or Associate Dean:</td>
<td>4/6/08</td>
</tr>
<tr>
<td>CPSP (for school personnel courses ONLY)</td>
<td></td>
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<tr>
<td>Associate Vice President and Dean for Academic Programs</td>
<td></td>
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</table>

**Distribution:** Academic Affairs (original), Department Chair and College Dean. Dean’s office to send original after approval to Academic Affairs, at mail zip 6016. An electronic copy must also be sent.

8/27/07
EEE 126 Design of Devices & Systems for Market Application

EEE Elective

2008 – 2010 Catalog Data: EEE 126. Design of Devices & Systems for Market Application. This course considers the key issues involved in the industrial design process, exactly as they would arise in real-world device applications. The emphasis of the course is on the design process for medical device applications, but that process is very similar for other market applications. Coverage includes analysis of product from conception through to delivery using actual industry examples. Topics include materials selection, safety, prototyping, pre-market testing, validation, liability, and learning from failure. Prerequisite: EEE 120, EEE 122, or instructor permission. 3 units.


Course Goals:

1. To build upon the fundamental electrical engineering analysis and design backgrounds provided by the EEE core and BME elective courses, and provide the student with practical engineering knowledge about the process of medical device design, applicable standards and FDA regulation.
2. To provide the student with “real-world” examples of the design process and experience in developing the design and testing protocols for new medical devices.

Prerequisites by Topic:

1. General knowledge of a structured programming language (i.e. C++, Assembly Language, MATLAB).
2. Basic understanding of biomedical instrumentation design.

Topics Covered/Course Outline/Evaluation:

Topics by Week

1. Biomedical Engineering Design Tools
2. Design Management, Documentation, and Reporting
3. Product Definition
4. Product Development
5. Computer-Aided (CAD) Design
6. Industrial Design and Human Factors Issues
7. Biomaterials and Material Selection
8. Safety Engineering: Devices and Processes
9. Prototyping and Testing
10. Quality Control, Reliability and Liability
11. Food and Drug Administration Rules and Regulations
12. Pre-market Testing and Validation
13. Regulations Tracking
14. Manufacturing and Quality Control
15. Licensing, Patents, Copyrights, and Trade Secrets

Topics will be illustrated using examples from actual medical device designs; sometimes presented by guest speakers from local industry.

Evaluation

One Mid-term Exam and one Final Exam* — 100 pts. each
(Note: Examinations will be ‘open book’ questions related to text readings, homework, and examples presented in class.
Medical Device Design Project Report — 50 pts.
Graded homework assignments — 50 pts.
(Note: Specific due dates for homework will be specified. No late homework will be accepted.)
Science and Design Content Distribution

Design – 3 units or 100%

Contribution of Course to the Professional Education Component:

1. Homework assignments include practical device design problems with realistic constraints.
2. Examples introduce students to the use of major professional engineering software tools in the design process.

Relationship of Course to Program Outcomes:

1. c. An ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability. This is the major focus of the course.
2. e. An ability to identify, formulate, and solve engineering problems. This course includes actual design examples and problem solving using realistic constraints.
3. k. An ability to use the techniques, skills, and modern engineering tools necessary for engineering practice. This course gives the students the ability to use industry-standard software to engage in medical device design and development.

Course Coordinator: John Oldenburg, EEE
Date: January 17, 2008