Office of the Registrar
FORM 40 REV. 11/09

PURDUE UNIVERSITY
REQUEST FOR ADDITION, EXPIRATION, OR REVISION OF AN UNDERGRADUATE COURSE (10000-40000 LEVEL)

Print Form

EFD 19-10

DEPARTMENT Biomedical Engineering   EFFECTIVE SESSION Fall 2011   201210

INSTRUCTIONS: Please check the items below which describe the purpose of this request.

- [X] 1. New course with supporting documents
- [ ] 2. Add existing course offered at another campus
- [ ] 3. Expiration of a course
- [ ] 4. Change in course number
- [ ] 5. Change in course title
- [ ] 6. Change in course credit/type
- [ ] 7. Change in course attributes (department head signature only)
- [ ] 8. Change in instructional hours
- [ ] 9. Change in course description
- [ ] 10. Change in course requisites
- [ ] 11. Change in semesters offered (department head signature only)
- [ ] 12. Transfer from one department to another

PROPOSED:

Subject Abbreviation BME
Course Number 48800
Long Title Preliminary Senior Project Design
Short Title Preliminary Senior Project Dsn

EXISTING:

Subject Abbreviation
Course Number

Abbreviated title will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY)

TERMS OFFERED
Check All That Apply:
[ ] Summer [X] Fall [ ] Spring

CAMPUS(ES) INVOLVED
[ ] Calumet [ ] Cont Ed [ ] Ft. Wayne [ ] Indianapolis [ ] N. Central [ ] Tech Statewide [X] W. Lafayette

CREDIT TYPE
1.Fixed Credit: Cr. Hrs. 1
2.Variable Credit Range:
Minimum Cr. Hrs
(Check One) To [ ] Or [ ]
Maximum Cr. Hrs.
3.Equivalent Credit: Yes [ ] No [ ]

COURSE ATTRIBUTES: Check All That Apply
1. Pass/Not Pass Only [ ]
2. Satisfactory/Unsatisfactory Only [ ]
3. Repeatable [ ]
Maximum Repeatable Credit: [ ]
4. Credit by Examination [ ]
5. Special Fees [ ]
6. Registration Approval Type: Department [ ] Instructor [ ]
7. Variable Title [ ]
8. Honors [ ]
9. Full Time Privilege [ ]
10. Off Campus Experience [ ]

ScheduleType	Minutes Per Mtg	Meetings Per Week	Weeks Offered	% of Credit Allocated
Lecture				
Recitation				
Presentation				
Laboratory	100	1	16	
Lab Prep				
Studio				
Distance				
Clinic				
Experiential				
Research				
Ind. Study				
Pract/Observ				

Cross-Listed Courses

2011 AUG -9 AM 9:43 OFFICE OF THE REGISTRAR RECEIVED

COURSE DESCRIPTION (INCLUDE REQUISITES/RESTRICTIONS):
The preliminary stages of design are completed during these lab hours. Students will work with their teammates to develop a problem statement with appropriate technical specifications, complete the relevant literature and market analysis, derive and justify a preliminary design, and outline a plan to successfully complete the project. The resulting preliminary design is presented and evaluated through an oral presentation and a written report.

*COURSE LEARNING OUTCOMES:
Students will have demonstrated the ability to: Integrate and apply knowledge and skills obtained in earlier course work with new concepts and practices essential to the design and testing of a system or device to meet desired needs. Implement the engineering design process and project management within the context of relevant design constraints. Effectively communicate skills in oral and written form, both individually and as part of a team. Explain/discuss realistic design constraints, including regulatory issues, societal influences, and ethical and professional responsibilities of biomedical engineers, as related to the engineering design process.

Calumet Department Head	Date	Calumet School Dean	Date
Fort Wayne Department Head	Date	Fort Wayne School Dean	Date
Indianapolis Department Head	Date	Indianapolis School Dean	Date
North Central Department Head	Date	North Central Chancellor	Date
George R. Wodicka — West Lafayette Department Head	2/22/11 — Date	[signature] — West Lafayette College/School Dean	7/25/11 — Date

[signature] West Lafayette Registrar   Date 8/11/11

OFFICE OF THE REGISTRAR

BME 48800

Engineering Faculty Document No. 79-10

February 3, 2011

TO: The Faculty of the College of Engineering

FROM: The Faculty of the School of Biomedical Engineering

RE: New Undergraduate Course, BME 48800 Preliminary Senior Project Design

The Faculty of the School of Biomedical Engineering has approved the following new course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

BME 48800 **Preliminary Senior Project Design**
Term offered: Fall, Lab 2, Cr. 1
Prerequisite: BME 30600
Co-requisite: BME 49000

Description: The preliminary stages of design are completed during these lab hours. Students will work with their teammates to develop a problem statement with appropriate technical specifications, complete the relevant literature and market analysis, derive and justify a preliminary design, and outline a plan to successfully complete the project. The resulting preliminary design is presented and evaluated through an oral presentation and a written report.

Reason: This course replaces one lab credit of the old BME 405. This new graded course is required of all BME students completing their senior design requirements and serves to focus effort on the preliminary design. We have distributed the essential elements of the BME senior design process from one required course to three required courses to be able to accommodate projects that extend over both the Fall and Spring semesters. This strategy will support a more diverse set of design projects that span all five of the major research areas within the Weldon School of Biomedical Engineering.

BME 48800 Preliminary Senior Project Design (1 credit lab)
BME 48900 Senior Design Project Lab (2 credit lab)
BME 49000 Professional Elements of Design (1 credit studio)

George R. Wodicka

George R. Wodicka, Professor and Head
Weldon School of Biomedical Engineering

APPROVED FOR THE FACULTY
OF THE SCHOOLS OF ENGINEERING
BY THE ENGINEERING
CURRICULUM COMMITTEE

ECC Minutes #17

Date 4/20/11

Chairman ECC R. Cipra

BME 48800

BME 488 Preliminary Senior Project Design
1 credit hour

Course Staff

Course Instructors:
Dr. Pedro Irazoqui
Dr. Sherry Voytik-Harbin

Lab Coordinators:
Dr. Marcia Pool
Dr. Allison Sieving

Teaching Assistants:

Course Operation

Course Description: The preliminary stages of design are completed during these lab hours. Students will work with their teammates to develop a problem statement with appropriate technical specifications, complete the relevant literature and market analysis, derive and justify a preliminary design and outline a plan to successfully complete the project. The resulting preliminary design is presented and evaluated through an oral presentation and a written report.

Class Attendance: Students are required to attend all laboratories. At the start of the semester there will be a laboratory safety training session. Students are required to attend this training session before they will be given access to work in the laboratory.

Facilities: Students' will have access to their assigned laboratory space Monday – Thursday 8 am – 11 pm, Friday 8 am – 6 pm, Saturday 1 – 6 pm, and Sundays 1 – 11 pm. It is expected that provided workspaces be kept in a clean condition prior to leaving for the day. Inadequately maintained spaces and/or failure to maintain a safe working environment can result in a temporary suspension of lab privileges.

Faculty and Staff Responsibilities: Professors, teaching assistants, and professional staff members will serve as consultants to your design team. Their role is to advise you in achieving your design goals. This is to help you implement your own original solutions. Please note that when you contact a faculty or staff member via email, you must include BME 405 in the subject line of your message. If you do not do so, your email may not be read. During the semester the course instructor will request team consultations on project progress.

Required Supplies: Laboratory Notebook with duplicate pages (e.g., National 43-644, 43-641, or 43-645)

Laboratory Attire: Safety regulations require that you wear long pants (or equivalent) and closed-toe shoes while working in the laboratory. Laboratory coats and safety goggles will be available.

Campus Emergency Response Procedures:

- Fire Alarm – Evacuate the building using the exits on the east side of RM 1087 or 1083 MJIS. Only gather personal items if it does not jeopardize your safety. Assist those who need help, if possible. Proceed to the front lawn of the Burton Morgan Building. Report to a course instructor your name before leaving the emergency assembly area.
- All hazards warning (examples of hazards: tornado (severe weather)/hazardous materials release/civil unrest/directed by police personnel) – When you hear the all hazards alarm immediately seek shelter. Continue to a safe location (typically the lowest level of the building in an area without windows).

Campus Emergency Policy: In the event of a campus wide emergency the class outline and course requirements may be subject to change. The course instructor will provide information in regards to changes in the course requirements or course schedule as a result of a campus wide emergency.

Course Assessment

Course Overview: This course will provide each student with a significant original design experience in biomedical engineering. This will be an iterative decision-making process in which basic science, mathematics, and engineering, are applied to solve a problem with clinical or biomedical research impact. Among the fundamental elements of the design process are the establishment of objectives and criteria, synthesis, analysis, construction, testing, documentation and evaluation.

Through this course, you will identify the problem, conduct literature searches and market analyses, define team responsibilities, select components for proposed design, and present in a written and oral format a preliminary design to address the proposed problem. These assignments have been developed to mimic a typical industrial design experience and to prepare you for success in the workforce as a biomedical design engineer.

BME 488 provides many opportunities for you to demonstrate mastery and accomplishment of the skills essential to a BME. Ultimately, students who successfully fulfill the course requirements will have demonstrated the ability to:

	Course outcome	**Relationship to BME program outcomes**
I	Integrate and apply knowledge and skills obtained in earlier course work with new concepts and practices essential to the design and testing of a system or device to meet desired needs.	1,2,4,5
II	Implement the engineering design process and project management within the context of relevant design constraints.	3
III	Effectively communicate skills in oral and written form, both individually and as part of a team.	6, 7
IV	Explain/discuss realistic design constraints, including regulatory issues, societal influences, and ethical and professional responsibilities of biomedical engineers, as related to the engineering design process	8,9

Academic Conduct: You are expected to behave in a professional and ethical manner in all aspects of this course. Plagiarism, cheating, or other acts of academic dishonesty will not be tolerated. Any infractions whatsoever will result in immediate expulsion from the course and a failing grade for the semester. Instances of plagiarism or cheating will also be reported to the Dean of Students Office to be recorded on your permanent academic record. If an individual behaves in any other manner that is unprofessional or unethical during the semester, the course instructor(s) reserves the right to fail the student for that as well. For more information, see the Purdue University Student Conduct Code at: http://www.purdue.edu/odos/adminstration/codeconduct.htm.

Grading Scheme: Grading is based upon the following assignments:

▪ Individual problem statement	10%
▪ Literature and market analysis	10%
▪ Team system design and responsibilities	8%
▪ Component selection analysis	10%
▪ Peer review	2%
▪ Design Journal	10%
▪ Preliminary design report	30%
▪ Oral presentation of preliminary design	20%
Total	100%

Grading Scale: The following grading scale is a guaranteed minimum; however, based upon individual student performance and/or the functionality of the final demonstration, final grades may be curved by the instructor.

GPA	Grade	Percent Range
4	A	≥93
3.7	A-	92 – 90
3.3	B+	89 – 87
3.0	B	86 – 83
2.7	B-	82 – 80
2.3	C+	79 – 77
2.0	C	76 – 73
1.7	C-	72 – 70
1.3	D+	69 – 67
1	D	66 – 60
0	F	≤59%

- During weeks with required training or instructor meetings, schedules will be posted and the students will select a time that they can complete the requirement.

Re-grade policy: Students have the right to contest grades throughout the semester. In the event that a student feels an assignment has been inappropriately graded, the student must submit a one page typed

document indicating the nature of the problem and an explanation for the re-grade submission. Along with this document, the original assignment must be returned to the instructor. Students have 1 week after the return of a graded assignment to protest a grade; after this time grade disputes will not be accepted. Papers submitted for a re-grade will be completely reevaluated (i.e., the entire paper will be re-graded, not only the portion under protest), which means that students may lose additional points for mistakes missed during the first grading process.

Course Assignment Descriptions:

Individual Problem Statement –
This assignment is designed to facilitate individual learning as it relates to the design problem. Specifically, this report will allow each student to become familiar with the objectives of the project and develop a draft solution to the problem prior to meeting in a team setting. The problem statement should not exceed 3 total pages; 2 pages should be dedicated to text and 1 page to your block diagram. The Individual Problem Statement should include the following:

1. *Problem Statement.* A brief problem statement should summarize the project objectives. These should define the goals of the project; in other words, describe what your team is to produce/build. All ambiguity in the customer's initial list of project specifications should be clarified in the problem statement.

2. *Customer needs.* Describe the needs that the customer has of the device in the format of technical specifications. Technical specifications describe the functional requirements of the device. Examples of specifications include: geometry, size, weight, kinematics, material, power, and etc. Typically these specifications should be quantifiable.

3. *Realistic Design Constraints.* Realistic design constraints should describe the constraints within which your device will be created and used; these address technical, economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability issues. For instance, the discussion of societal significance may: 1) describe the needs or demands met by the device and 2) explain the benefits that the system would provide to the medical device company, the practice of medicine, and society at large.

4. *Initial Proposed Solution.* Your initial solution to the problem should include a block diagram and description for the customer to review. This diagram represents your individual attempt at an initial design solution. Blocks should represent necessary functional subsystems and components to achieve the project specifications. Descriptive text should accompany each block in the diagram. Note that the description should relate the block diagram back to the structure/function/physiological parameters of the problem statement. Specific details as to the types of material or parts to be used in constructing the system or operating procedures of the control systems are ***NOT*** required at this early stage. However, you are expected to identify how your system components will interface with biological tissues/cells and indicate appropriate considerations relevant to your design choices.

5. *Relevant anatomy and physiology.* Describe the anatomy, physiology, and associated physiological parameters which are relevant to your project. This should include, but is not limited to, electrical, physical, mechanical, and other properties.

This document will evolve over the semester. You will merge your ideas with your teammates in the Preliminary Design Report and make changes to the text up to the Final Written Report.

Literature and Market Analysis –
This collaborative document should be used to determine if there is any missing background information that is important for the development of a novel functioning device. The report must be no longer than 4 pages, including figures and tables.

Literature Analysis
The goal of the literature review is to explain what has been accomplished by others in the area to date, what the current state-of-the-art is in relation to your project, and the rationale and significance of your design approach. Your review must include:

1. A brief historical overview of your field, citing the most important accomplishments that have brought the field to its current state of knowledge. This paragraph should be followed by a more detailed one, which provides an overview of the current state of knowledge.
2. A description of the limitations of the current approaches or important gaps (questions) that need to be addressed in order to move the field forward/address these problems.
3. A clear rationale for seeking an engineering solution to this problem.
4. Indicate how the solution will affect society (i.e., who will benefit and how?).

The following web page may be helpful in your search: http://www.ncbi.nlm.nih.gov/entrez/; it is a search engine provided by the U.S. National Library of Medicine that includes over 16 million citations from MEDLINE and other life science and engineering journals on biomedical research.

Market Analysis to Support Engineering Design
This portion of the assignment defines the customer and clinical need for the product or service, and identifies the potential markets. These issues represent some of the realistic constraints which may influence your design. Specific issues that must be addressed in your market analysis include a discussion of:

1. What is the market need and clinical value for this product?
2. What is the market size for this product? Is the market saturated? Is the target market broad-based and multi-faceted or a focused niche?
3. What competitive products and services compose the market landscape? What are the limitations of these products and services that are currently available?
4. What is the cost that customers would be willing to pay for this product? The answer to this question must include rationale and supporting data for the price you list.

Knowledge Gap and Product Gap

1. How does the design address a problem that people in the field have been trying to solve?
2. What aspects of the design would be surprising or unexpected to an expert in the field?
3. What aspects of the design could give this product a competitive edge in the marketplace?

Team System Design and Responsibilities –
This document is provided to the customer to summarize your team's system design and technical capabilities. The document briefly describes your team's system design and documents how each team member will

contribute to the project. The assignment should include the following information, and written text must not exceed 4 pages:

1. *Description of System Design.* Using a block diagram as a reference point, briefly describe how your system design works and explain how it meets the problem specifications and is within design constraints. The block diagram must be computer-generated. At this stage, it is anticipated that there will be multiple ways to tackle aspects of the system design. It is not necessary (or even possible) to decide upon the optimal approach at this early stage of the design process. However, it is important that this document illustrate to the customer that you have considered all aspects of the system and have reasonable design approaches in mind, and that upon further experimentation, analysis, and research, an optimal design will be chosen.
2. *Evolution of Design.* Explain your design choices in light of the design criteria and relevant realistic constraints, and describe how they were arrived at, whether they evolved from a compromise between proposed solutions, stemmed from a single named originator, or resulted from technical analysis. Also, you should include a brief statement to place your design within the context of your literature and market analysis to establish how your design will utilize, integrate, or improve upon previous developments in the field.
3. *Team Responsibilities.* To efficiently complete the design project, it should be broken down into smaller design tasks which when integrated will meet the design criteria. Each design task should have only one responsible party (although multiple team members may assist with the task). ***Each team member must have sole responsibility for at least one functional subsystem***. In a table format, for each team member list their responsibilities to contribute to the design process, the team member's qualifications for those tasks, and identify what type of expert (engineering, science, liberal arts, business type) you will seek assistance from should your team run into problems. Some supporting text should be provided to briefly describe the table and elaborate, as necessary, on selected items. In addition, think about persons outside of your team you may choose to contact for assistance during your design process. Which experts would you like to meet with? How would you want them to assist you in your design?
4. *Gantt Chart.* A timeline showing the status of the design process, the sequence of the design process, the estimated durations needed to complete each portion of the design, the time anticipated to integrate all aspects to produce a functional design, and the anticipated date of completion for each deliverable. This should describe the status of the overall project, the milestones your team must meet, and indicate individual responsibilities. It is a good rule of thumb in estimating durations of tasks to estimate the optimistic duration and then multiply by a factor of 3 to 7. In industry, the ability to provide accurate time estimates is a highly valued skill of a good engineer and manager. With practice, you will learn the appropriate multiplication factor for your team. Of course, unanticipated issues do arise but these factors help to mitigate schedule slippage. (Unfortunately, the deadline rarely slips.)

The customer will evaluate this document and provide feedback. It is not uncommon for a customer at this stage to interact with the design team and begin some negotiations. For example, they may provide additional technical specifications (that may have inadvertently been omitted from the first round of problem specifications) or request additional system capabilities that may be accommodated with your proposed approach, they may even modify the team composition or redistribute the workload if they perceive either a lack in expertise or an under-utilized team member(s).

Component Selection Analysis –

As a first step towards building a system, you must analyze, assess, and select a variety of potential components (e.g., parts) for use in your team's design. You must identify a set of potential components to use in your team design and provide text which clearly describes the functionality of these potential parts and how they would work in the system (i.e., how each is linked to achievement of the requirements). You must then evaluate the potential components for each major system operation in regards to their cost, ability to meet the project specifications, and other relevant constraints. For instance, if part of your system requires that you maintain a constant temperature of a liquid solution in a system, you would evaluate things such as a hot plate, a water bath, etc. In this assessment, you are expected to use a quantitative decision-making tool (e.g., decision trees, Pugh charts, etc.) to come to your final component decisions. For each component, you are expected to either present a decision resulting from your analysis or discuss the decision making process you will use to come to a final decision. This document will guide your discussion with company representatives when you seek approval to order system parts.

Peer Review –

Students will conduct a self and peer evaluations on participation in team endeavors. Feedback from these evaluations will be used to help guide instructor/student interactions. Each student will be given a summary feedback from the peer reviews; however, all evaluations will remain anonymous. Results are factored in as part of your overall course grade. Peer reviews will be evaluated both by the student's ability to provide constructive comments to peers as wells as the student's peers' impressions of their team performance. Students will be evaluating for the following areas::

- Team player (description: an ability to assist teammates in their tasks as needed; reliable team member overall).
- Work ethic (description: attitude; effort; participation in team tasks; preparation in team meetings).
- Goal setting and achievement of goals (description: sets goals for team assignment, in lab activities, etc; assists team in meeting goals).
- Communication (description contributes ideas/opinions/concerns to the group; listens to and shows respect for others' input; able to negotiate/compromise well with team members).
- Innovation (description: provides novel concepts to solve solutions).
- There is an additional section that addresses areas in which improvement is needed.

Design Journal –

Each team member must maintain a design journal to document their individual contributions to the design project. The purpose of your design journal is to provide a complete and chronological record of your work on the BME 488/489/490 sequence; this will include individual literature searches, personal planning sessions, team planning sessions, laboratory sessions, etc. Ultimately, each step you take towards achieving a design solution must be documented in your journal. Each entry should include date, time, location, and participants in the session. It is recommended that the standard notebook layout with a brief statement of the objective of the activity, the procedure followed, and results and conclusions is followed. Journals will be graded once during the course. At each submission date, the duplicate journal pages and hard copies of any attached documentation will be turned in for storage in a back-up location. Grading of your journal will be primarily determined by whether a person versed in the field but unfamiliar with your work, could duplicate your efforts with only your journal to go by.

BME 48800

Preliminary design report –

The purpose of the Preliminary Design Report is to convince the customer that your proposed system will meet product specifications, will be operational by the conclusion of the BME senior design sequence, and will be economically favorable. Your written report must demonstrate that your team has sufficient knowledge in the required technical areas and the proposed design is feasible.

The assignment should include the following:

1. *Problem statement.* Restate the customer's requirements, the state of the art in related products, the market need, and discussion of realistic design constraints. This should evolve from a revision and combination of the team members' **Individual Problem Statements** and the teams' **Literature and Market Analyses.**
2. *System Design.* Provide a brief overview of the entire device. The following areas should be explored in this section:
    a. An updated block diagram; discuss the function and specifications of each block/system component in the diagram.
    b. Discussion of design challenges associated with the devices interaction with living/biological systems.
    c. Justification of design choices in terms of the devices interaction with living/biological systems.
3. *Subsystem Design Description.* Provide a technical description of your system design (derived partially from revised and integrated text from the **Team System Design and Responsibilities** and **Component Selection Analysis** documents). Description for each subsystem should contain the following:
    a. The engineering principles, mathematic relationships, and/or biology/physiology principles which explains how the subsystem operates.
    b. Evolution of the subsystem design.
    c. System integration plans and considerations (i.e., how have you thought about final system integration in each step of your design?).
    d. Testing Plans and Results. Describe all subsystem tests, system functionality tests and system calibration protocols and data. For each, you must provide a description of the protocols and procedures to be used, describe how data will be recorded, and indicate methods to interpret recovered data.
4. *Whole system description.*
    a. Address how all the subsystems will integrate into a final product and how the design satisfies customer specifications, technical specifications, and realistic design constraints.
    b. Unresolved Issues. Summarize major unresolved issues related to the system design or integration. Indicate strategies you will use to overcome these problems.
    c. Testing Plans and Results. Description of appropriate protocols and procedures for proposed functionality tests and calibration practices.
    d. Evaluation of systems capability to meet customer specifications, realistic design constraints, and technical requirements.

5. *Appendix.*
    a. Gantt chart image. This should be updated from the **Team System Design and Responsibilities** document. Include supporting text if needed. Team is to update the customer on the status of the project, milestones the team is working towards, and individual responsibilities for each team member.
    b. Cost Estimate. Provide an estimate of the cost of the completed prototype system and testing assays (not including labor). Include a list of the major components of your system, with product numbers, vendors and estimated costs. At this point, not every system component may be specified so use your best estimate for unspecified parts and provide brief text describing how these estimates were determined.
    c. Team Responsibilities. An updated description of team responsibilities from the **Team System Design and Responsibilities** document. This should include a table with team responsibilities and supporting text.

Oral Presentation of Preliminary Design –

The Preliminary design presentation is a 10 minute power point presentations which summarizes your team's design. The presentation will be made to and evaluated by BME faculty, company representatives, lab coordinators, and TAs. Following the presentation will be a question and answer session. The entire session for each team will last no more than 20 minutes. Your team should be prepared to address detailed technical and financial questions about your system.

The presentation order will be determined by a random drawing on the first day of presentations; therefore you must be ready to present on the first day of presentations. **Your team's power point file must be submitted (via email) to the laboratory instructor 2 hours prior to the start of the presentation.**

Design reviews are intentionally challenging. This mimics real world design reviews where the customer must decide after the review if they want to provide you with substantial funding to generate a complete prototype working system. Thus they will ask questions, interact, and negotiate on system specifications to ensure that they have a reasonable level of comfort to proceed to the final design stages. In extreme cases, the customer may fire a team or force them to start over should the design be totally insufficient.

The week prior to the presentations the course instructor will post a sign up form for teams to select a presentation slot that works in their course schedule.