Senior Design Process

Senior design consists of two required courses, Design I and II. In Design I focuses on the engineering design phase of a project development (after specifications have been largely determined and prior to manufacturing). Through lectures and hand-on-experience (including a mini-project and the main senior design project) students are introduced to: working on teams, design process, planning and scheduling (time-lines), technical report writing, proposal writing, oral presentations. Design II focuses on the business, marketing, and regulatory aspect of design including: ethics in design, safety, liability, impact of economic constraints, environmental considerations, manufacturing and sales.

As illustrated below the product development process was traditionally segmented and preceded sequentially. This process has not largely been replaced by simultaneous (concurrent) design process. BME Senior Design is still divided along these lines. In BME 405 (Design 1) students will learn engineering design principles and apply them to design specification previously generated by the course director or project sponsor.

Factors that determine good design:

1) Quality – A design should meet all specifications
2) Cost – Both the design process and manufacturing process (determined by the design) should be cost effective.
3) Time – The design process should progress in a timely fashion. This requires good project management and an efficient design process.

The central steps in Design are:
1. Determine design specifications/requirements, understand the problem.
2. Prepare a project proposal.
3. Prepare an initial timeline for the project. This is subject to change.
4. Considers existing/alternative solutions, prior art search.
5. Generate multiple (alternative) solutions
6. Evaluate alternatives by comparing them to design requirements and to each other.
   Steps 5-6 are iterative and can be conducted using:
   a) Brain-storming, block-diagram, paper design
   b) Engineering/quantitative analysis (e.g. computer modeling/simulation)
   c) Prototyping, components and different levels of abstraction
7. Decide on applicable solution
8. Communicate results
The entire design process must be carefully documented.
All the following steps are critical steps in the design process; failure to comprehensively complete any one of these steps or meet milestones on time, can result in project failure (regardless of final device performance).

The Design Process: Flexibility/Cost and Time
The above chart summarizes a central concept in practical design projects. At the beginning of a project (Time Point 1) there is maximum flexibility in the potential design approaches; however, at this point little is known about what design approaches will be most effective. As the design process continues time and cost (personal, material, prototyping) is committed to evaluating different design approaches; in the process, the engineer learns more about what design approaches are most effective. But the engineer learns only about those designs that are tested/prototyped and so the engineer is ‘committed’ to basing further improvement on existing (and hence less flexible) designs.

Because of limitations in time/cost, the approach generally taken in the design process is to start with a ‘brain-storming’ period where multiple ideas can be rapidly evaluated with little time/cost commitment. This is the most flexible design stage. From the brain-storming stage, the most promising designs are selected based on the engineer’s intuition and experience; a minimum is known at this stage about which designs will be most effective. These designs are not quantitatively evaluated. Next, often the cheapest and most rapid method for initial quantitative evaluation of engineering analysis and computational modeling. From this theoretical quantitative analysis, the most promising (a smaller set) designs are selected. At this stage basic physical prototypes of the devices or of device components are manufactured, often on smaller scale or using cheaper, readily available, or more malleable supplies than intended for the final product; this is done to reduce the time and cost of this stage of development. The basic physical prototypes/components are now evaluated and only the most promising (usually one or two) designs are selected. A full prototype is now constructed. The construction and testing of the full prototype is the most time consuming and costly stage. At this stage, most design decisions have been made and the restarting the design process from an early stage may not be practical because of already committed costs/used time. It is only through testing of the full prototype(s) that the engineer can precisely determine how well the device meets the product specifications; thus at this stage knowledge about device performance is maximized. It should be emphasized changes in the design are made throughout the design process. The example process outlined above aims to optimize time and cost.

**Team selection, reporting**

Students are divided into groups of 3. Teams of 4 may be allowed with the course directors’ permission. Students may select their own groups. If any student is unhappy with the team selection process they may notify the course directors – they may ask the course director to keep their comments confidential. The course directors reserve the right to select/modify any group. It is in the student’s interest to notify the course director of any team selection concerns as soon as possible.

Each team will select a student group leader. It is the group leader’s responsibility to delegate tasks. Each group will identify the group leader to the course director, the group leader then may not be changed without the course directors’ approval. It is the entire group’s responsibility to ensure project is completed successfully.

Each team will be assigned a TA (Biomedical Engineering Graduate Student). The TA responsibility is to provide general guidance and technical support. The TA may be consulted about specific design approached or methods to evaluate design approaches. Each group must
update the TA on a weekly basis as to their progress; this may be done by e-mail. If no progress has been made, the TA must still be notified. It is not the TA responsibility to ensure the project is successful, on time, etc. The TA is not the group supervisor and should be treated as a consultant. Students must work around the TA’s schedule and be considerate of the TA’s time.

Each team must provide a written progress report to the course director on a monthly basis. The report must be signed by the TA.

Should individual students have serious concerns about performance of the group: 1) group members should first contact the group leader; 2) if the group leader cannot resolve the problem or the student feels the group leader is not responsive to their concerns they may the forward their concerns to the group TA.

**Time-line**

Senior design project initiate on the day of project selection. Key milestone and deadlines are defined by the course directors and are not flexible. It is the responsibility of the design team to guarantee that ALL key milestones are met.

Excluding course defined milestones, the time-line may be modified during the course of the project. If the team falls behind schedule, the time-line must be modified immediately. The time-line must constantly be up to date.

The time-line is divided into tasks. The sections outlines below constitute the main project tasks but may be divided into sub-tasks. Sub-tasks may overlap in time

**Specifications**

One of the most important parts of the design process is determining the requirements that the design project must fulfill. Before the design of a project, a statement as to how the device functions is required based on operational specifications. Specifications determine the device to be built, but do not provide any information about how the device is built. Specifications also include a technical description of the device, and contain all of the facts and figures needed to complete the design project.

Prior to the design of a project, a statement as to how the device will function is required based on operational specifications. These specifications determine the problem to be solved. The operational specifications completely describe and define the project. Specifications are defined such that any competent engineer is able to design a device that will perform a given function. If several engineers design a device from the same specifications, all of the designs would perform within the given tolerances and satisfy the requirements; however, each design would be different. Manufacturer’s name or components are not necessarily stated in specifications. For example, specifications do not necessarily list specific mechanical/electronic components since use of these components implies that a design choice has been made.

If the design project involves modifying an existing device, the existing device is fully described in as much detail as possible in the specifications (including through references to published material). In this case, it is desired to describe the device by discussing specific components, such as the microprocessor, displays, and electronic components. This level of detail in describing the existing device is appropriate because it defines the environment to which the
design project must interface. However, the specifications for the modification should not provide any information about how the device is to be built.

Though the project sponsor provides product specification it is the responsibility of the student to ensure the specifications are consistent, realistic (in the time frame of Senior Design and given the intellectual/material/space/financial resources available to students), and fulfill a practical biomedical need. Concerns about specifications provided by the sponsor should be addressed first to the course directors and (as the course directors discretion) to the project sponsor.

Specification may be divided in required (minimal, inflexible) and desired (not critical but improving the device performance in a practical way).

Specifications written report qualitatively describes the project as completely as possible, and how the project will improve the life of the disabled person. It also provides motivation for carrying out the project in the specifications. The following issues are also addressed in the specifications:

What will the finished device do?
What is unusual about the device?

The students must prepare a report of these specifications. The specification provided by the sponsor would for a basis for this report. This specifications report must be approved by the course directors and will be forwarded to the project sponsor.

**Project Proposal**

Each group writes a proposal whose purpose is to clearly define the objective of the project. Without exaggeration, the proposal should be written in a manner that would motivate ‘upper management’ to fund the project. The proposal introduces the project in layperson terms, examines the market place identifying existing products that have similar specifications, and presents a preliminary budget and timeline.

Preparing the project proposal present the students with the first opportunity to interact with the project sponsor if they require clarification not obtainable through other means. The project sponsor is provided with the project proposal. The project sponsor is not responsible to evaluate the proposal.

The project proposal includes the specifications provided by the sponsor but may include additional specification and design requirements. And example (iPOD ECG) is provided.

The project proposal must be clearly, concisely, carefully, and professionally laid out. Given these constraints, there is no specific page limit and students are given flexibility in proposal organization (e.g. section headings)

**Prior Art**

Students must conduct an exhaustive search of prior art. This includes 1) general search engines (Google, yahoo); 2) scientific/medical search engines (Pub Med, ISI, IEEE); 3) relevant web-based resources (http://www.abledata.com; bmesource.org; http://enablingdevices.com); 4) Patent office; 5) relevant company web-pages. Students may request of the project sponsor for any information related to prior art.
Projects accepted for Senior Design are assumed not to completely reproduce prior art; however, *it is the responsibility of the students to determine if this is the case.*

In many cases, devices which meet a portion of the device specifications may exist. Discovery that an existing device already meets the project specifications is not a failure on the part of the design team. Rather, if the team proceeded with the design, ignorant of the existing technology, theirs efforts may be wasted. Should an existing device be found, this can be reported to the project sponsor/course director at which point 1) the device specification may be modified or 2) students will select a new project.

Generally, an invention is something that is found by reaching out into the unknown. Since an invention cannot be defined by describing something that is still unknown, the only alternative is to state what is not an invention. This is done by defining what is in the prior art.

Prior art may be defined very broadly as the entire body of knowledge from the beginning of time to the present. In most patent laws, **prior art** or **state of the art** is all information that has been disclosed to the public in any form before a given date. However, under United States patent law, secret prior art, such as secret sales, qualifies as prior art in certain circumstances. In Europe, prior art does not include information kept secret, whether from trade secrecy or just a simple lack of interest in publication.

In most patent laws, prior art is expected to provide a description sufficient to inform the average worker in the field (or the man skilled in the art), published in fixed form and made available in public libraries. Again, in most patent laws, prior art does not include unpublished work or mere conversations (though according to the Europe Patent Convention, oral disclosures also form prior art – see Art. 54(2) EPC). It is disputed whether traditional knowledge (e.g. of medical properties of a certain plant) constitutes prior art.

The term prior art is mainly used in the patent field. Patents disclose to society how an invention is practiced, in return for the right (during a limited term) to exclude others from manufacturing, selling, offering for sale or using the patented invention without the patentee's permission. Patent offices deal with prior art searches in the context of the patent granting procedure. To assess the validity of a patent application, patent offices explore the prior art that was disclosed before the invention occurred (in the United States and all first-to-invent patent systems) or before the filing date (in Europe and all first-to-file patent systems).

Some of recommended sources were students might conduct an exhaustive search of prior art are:

**Internet:**

a) General search engines (Google, yahoo, etc);

b) Scientific/medical search engines (Pub Med, ISI, IEEE, BioOne Journals Online, JSTOR (General Science, Mathematics and Statistics Collections), Kluwer Online, LINK - (from Springer Publishing Group), Oxford University Press, Proquest Direct, ScienceDirect - (from Elsevier), Synergy - (from Blackwell Science and Munksgaard), Wiley Interscience


Design Magazines (BME design related magazines as http://www.medicaldesign.com/, Medical Device & Diagnostic Industry, Medical Product Manufacturing News, IVD Technology, MX, European Medical Device Manufacturer, Medical Electronics Manufacturing, Pharmaceutical & Medical Packaging News, Medical design technology, Medical Device & Diagnostic Industry magazine, etc)


Relevant company web sites: these web sites are specific to the design project and can be searched using the general purpose search engines in the internet.

Prior Art and design theory might be also found in books and Design texts in BME, EE, ME, Comp Eng. as:

Paper Design and Engineering Analysis

The next phase of the design is the generation of possible solutions to the problem based on the specifications, and selecting the optimal solution. This involves first creating a paper design for each of the solutions and evaluating performance based on the specifications. Since design projects are open-ended, many solutions exist. The paper design stage of the design process is challenging because of the creative aspect to generating problem solutions.

In the paper design stage many potential solutions can be rapidly suggested and discussed. The most promising of these are subject to more time involved engineering analysis.

Engineering analysis involves more detailed and quantitative evaluation of each design proposal. This stage often involves computer simulations for example using PSpice for circuit analysis. Other situations require a potential design project solution be partially constructed or bread-boarded for analysis and evaluation.

The specifications previously described are the criteria for selecting the best design solution. In many projects, some specifications are more important than others and trade-offs between specifications may be necessary. In fact, it may be impossible to design a project that satisfies all of the design specifications. Specifications that involve some degree of flexibility are helpful in reducing the overall complexity, cost and effort in carrying out the project. Some specifications are absolute and cannot be relaxed whatsoever.

Most projects are designed in a top-down approach similar to the approach of writing computer software by first starting with a flow chart. After the flow chart or block diagram is complete, the next step involves providing additional details to each block in the flow-chart. This continues until sufficient detail exists to determine whether the design meets the specifications after evaluation.

After analysis of all possible solutions, the optimal design selected is the one that meets the specifications most closely.

Construction and Evaluation of the Device Prototype

After selecting the optimal design, the student then constructs the device. Generally only a single design is selected for construction, however, multiple design approaches (or specific component designs) can be considered if the engineering analysis cannot distinguish an superior design.

The best method of construction is to build the device module by module. By building the project in this fashion, the student is able to test each module for correct operation before adding it to the complete device, composed of previously tested modules. It is far easier to eliminate problems module by module than to build the entire project, and then attempt to eliminate
problems. Students should be aware that combining independently function modulates may introduce problems as a result of the interfacing.

Design projects are analyzed and constructed with safety as one of the highest priorities. Clearly, the design project that fails should fail in a safe manner, a fail-safe mode, without any dramatic and harmful outcomes to the client or those nearby. An example of a fail-safe mode of operation for an electrical device involves grounding the chassis, and using appropriate fuses; thus if ever a 120-volt line voltage short circuit to the chassis should develop, a fuse would blow and no harm to the client would occur. Devices should also be protected against runaway conditions during the operation of the device, and also during periods of rest. Many specifications will require that failure of any critical components in a device should result in the complete shutdown of the device or generation of a warning signal.

Documentation

Each individual student is required to carefully document the entire design process. This includes all stages of project planning, brain-storming, and design evaluation. The documentation must in approved notebooks, in black ink, in sequential (no blank) dated pages. Students working in groups are not required to copy information across books; it is sufficient that each step is documented in a single notebook. Information can be copied. Student notebooks will be evaluated on an individual basis.