Ermine Biomedical
Solutions, Inc.

August 12, 2005

Dear Sir or Madam:

EBS specializes in the manufacturing and development of products for use in emergency rooms. We have an existing line of orthopaedic products for use with broken arms, particularly those of young (ages 5-12) children. In particular, we have a line of implantable plates for fracture fixation.

Since patients with fractures requiring internal fixation are only a small fraction of the total number of injuries each year, we would like to expand our product line to serve patients who only require casts. This is a well-established market and we will need some novel products to compete with the existing firms. Therefore, we would like to have your teams develop a series of potential products for our firm.

In general, we are looking for products that fall into one of the following three categories, (1) improve the existing product (e.g. a new material for the cast), (2) develop a product that makes living with a cast better (e.g. an arm scratcher for inside the cast), or (3) develop a product to improve the survivability of the existing designs (e.g. a waterproof covering for the cast, allowing the wearer to take a shower). The ideal product will be inexpensive to produce, but will have good sales price, yielding high profitability.

As you develop your products, I would ask you to consider the following constraints

- This product will be sold to hospitals for use with children in the 5-12 year old age group.
- While the product can be gender specific, versions need to be available for both boys and girls.
- The product will have to last until the cast is removed, typically around a month. In the past this has proved to be a challenge, since at the end of their recovery period, these children are active in the playground and sports.
- Since the product will be used with relatively young children, product safety is critical.
- The product will, in the end, be paid for by either the insurance or by the parents of the child. In the former case, it will need to reduce their costs by protecting the cast. In the latter case, it will need to be sufficiently attractive to create cash sales.
- The product should have a final production cost of no more than $10 each (we will sell them for 2-3 times that amount)

Since we will to sell these products to the public, protecting the designs through the appropriate intellectual property laws, either copyright or patent depending on the nature of the design, is essential. Therefore, we request that you document both your design and the process by which it was created. These documents will protect us, if we are asked to defend the designs in court. In addition, I would ask that you keep me informed of your progress through a series of weekly progress memos.

Sincerely,

Mordecai Fleam, MD, PhD
President and Chief Executive Officer

Project: ______________________________ Page ________________

Date ________________

Comments: ____

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Design Engineer: ______________________ Witness: ______________

A common mistake that people make when trying to design something completely foolproof is to underestimate the ingenuity of complete fools.

- *Douglas Adams*
Mostly Harmless

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The Design Process:

Design Project for

Ermine Biomedical Systems

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Your teams have been...

- Contacted by Ermine Biomedical Systems to develop a new line of products for broken arms (see the attached letter from EBS)
- Each design team
  - will create a new product
  - document your product and process
  - report regularly to the instructor and EBS

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Document your design!

- Engineers document their work for a range of reasons
  1. It helps you remember what you did
  2. Documentation will tell the company what you did
  3. It will tell the company how to build your design
  4. It will help protect your ideas from being stolen, if someone else comes up with a similar idea later
- Documentation will help you get a good grade ☺

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Document your design

- Typically design engineers write 3 kinds of documents
  1. A design notebook - maintained *every* day
  2. Memos - to keep their team and their bosses informed of the current status
  3. Reports - either proposing projects or documenting completed designs

The Laboratory Notebook

- Maintain a laboratory notebook every day
  - Start each day and design step on a new page
  - Number and date each page
  - You and a witness should initial the bottom of each page
  - Write down what you did (pictures and drawings help)
  - Write down any decisions that were made

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Memos

- Memos are *short* documents (1-2 pages maximum) to bring the reader up to date
- Memos should contain...
  - What you planned (1 paragraph)
  - What you actually did (and why it differs from what you planned) (1-2 paragraphs)
  - What you are going to do next (1 paragraph)

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The Design Report

- Write up a design report containing
  - A short cover letter
  - A one page summary of your design
  - A table of contents
  - A background section
  - A description of your goals and specifications
  - Detailed documentation of your design
  - An appendix (see the next slide for its contents)

The Design Report

- Your Appendix should contain
  - A list of all its components, where they came from, and what they cost
  - Drawings of all of the parts of your design
  - An instruction sheet describing how to use your product
  - A copy of the evaluation and improvement information from stage 6
  - Copies of the pages in your lab notebook

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What is Design?

Engineering design is...

- The organized *process* of creation
- A *process* to create a product that...
  - meets a given set of goals
  - functions within a set of constraints
  - a method that works

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What are the qualities of good design?

- Functionality
- Quality
- Safety
- Manufacturability
- Maintainability
- Economical

What are the qualities of good design?

- Ergonomics
- Ease of use
- Appearance
- Environmentally friendly
- Societally Appropriate

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So… How do we get there?

The Stages of Design: The 7 Ds

- Stage 1: Definition and specification of the product
- Stage 2: Data acquisition and analysis
- Stage 3: Discussion of solutions
- Stage 4: Development and testing of the models

The Stages of Design: The 7 Ds

- Stage 5: Decide on the best design
- Stage 6: Design implementation
- Stage 7: Do it better next time

Stage 1: Definition and specification of the product

- Develop a product that improves life for people with broken arms
- You could...
  - Develop a new kind of cast
  - Improve an existing kind of cast
  - Develop a product that makes living with a cast easier
  - Develop a product that makes a cast look better

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Define the product

- What problem are you going to fix?
- What does the product do?
- How does it perform its function?
- How long does it have to last?

The product specifications

- What are the product's…
  - Size?
  - Shape?
  - Function?
  - Durability?
  - Maximum Cost?

Stage 2: Data acquisition & analysis

- Answer the following questions
  - What does your product need to do?
  - What do existing products do?
  - What do they look like?
  - How do they work?
  - What are they made of?
  - How do they meet your specifications?

Where can I find the information that I need?

- The library
  - Books
  - Research and Trade Journals
  - Newspapers
  - Government publications
  - Engineering and medical textbooks

Where can I find the information that I need?

- On-line sources of information…
  - Patent search
  - Medical associations
  - Governmental agencies
  - Manufacturers of similar products

Where can I find the information that I need?

- People including...
  - Health care professionals
    - Nurses
    - Doctors
    - Surgeons
  - Patients
    - Yourself
    - Friends
    - Family

Stage 3: Discuss & generate creative ideas

- The Rules of Brainstorming
  - Think outside the box
  - Invite different kinds of people to generate ideas (e.g. friends, engineers, doctors, nurses)
  - Write down every idea that comes to mind (there are no bad ideas)
  - You should have a minimum of 3-4 potential ideas per group member
  - Don't pass judgment on ideas or people

Sifting through your ideas

- Sifting the Ideas
  - Examine the list to eliminate duplicates
  - Clarify each item on the list
  - Evaluate each of the ideas
  - Consider combining ideas
  - Pick the best 3-4 ideas

Refining your best ideas

- Refine the Best 3-4 Ideas Using...
  - Common sense
  - Economic analysis
  - Engineering analysis of product
- Avoid existing designs and patents
- You may need to eliminate or add solutions at this stage

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Stage 4: Develop & test your ideas

- Build quick and dirty models of 3-4 best choices
- Models can include
  - Mathematical models
  - Computer models
  - Scale models and mock-ups
  - Diagrams and graphs

Evaluate your ideas

- Things to consider in evaluating your idea
  - Does it meet the product goals?
  - Does it meet the product specifications
  - Would I want one?
  - Would I pay for one?
  - Does it meet the qualities of good design

Stage 5: Decide on your design

- Decide objectively which design you will present to the class/Dr. Fleam
- A good way to make an objective decision is to use a "decision table."

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Decision Tables

1. List your product specifications
2. Add any other important criteria from the list of "qualities of good design" to this list
3. Put them in order of importance from most important to least important
4. Assign a point value to each item on the list
5. Evaluate each product and assign a number of points for item 1 on the list
6. Repeat for item 2 and until you have completed your list
7. Add up the points for each item to choose the best design

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An Example Decision Table

Criterion	Points	Design 1	Design 2	Design 3
Performance	30			
Cost	25			
Production	20			
Appearance	15			
Safety	10			
Total	100			

Stage 6: Design implementation

- Make any final improvements to the best design (don't be afraid to take ideas from your other designs)
- Determine final color, appearance, etc.
- Build your final version of the design (this one should look nice)

Stage 6: Do it better

- The goal of stage 6 is to improve your designs
- In it you examine 3 topics
  1. People
  2. Process
  3. Product
- It is not a complain, whine, and moan session

Stage 6: Do it better

- You should ask the following questions for each of the 3 categories:
  - What did we do right? (how do we do it again)
  - What did we do wrong? (how do we stop from making the same mistake again)
  - How do we prevent the problems from occurring again?

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ENGINEERING DESIGN CHALLENGE: BIOMEDICAL ENGINEERING AND BIOMATERIALS

A common mistake that people make when trying to design something completely foolproof is to underestimate the ingenuity of complete fools.

- Douglas Adams
Mostly Harmless

What is the problem?

This case study is presented as a contract with a biomedical supply company (Ermine Biomedical Systems, Inc.) to develop a series of new projects. The class should be divided into teams of 2-4 students. Each team will develop one new product for the company. A letter from the company president has been included. This letter combined with the associated PowerPoint slides will give the students the information they need to complete the project. The materials below are found on the attached PowerPoint presentation in an outline format. Explanatory materials are in italics.

Your teams have been...

Contacted by Ermine Biomedical Systems to develop a new line of products for broken arms (see the attached letter from EBS)

Each design team
• will create a new product
• document your product and process
• report regularly to the instructor and EBS *In addition to the final design report, ask the students to write a memo every week to the president of EBS, Dr. Fleam.*

Document your design!

Engineers document their work for a range of reasons

1. It helps you remember what you did *Ask students to try and remember the details of a project that they completed the previous year.*
2. Documentation will tell the company what you did
3. It will tell the company how to build your design
4. It will help protect your ideas from being stolen, if someone else comes up with a similar idea later

Documentation will help you get a good grade•

Document your design

Typically design engineers write 3 kinds of documents

1. A design notebook - maintained *every* day
2. Memos - to keep their team and their bosses informed of the current status
3. Reports - either proposing projects or documenting completed designs

The Laboratory Notebook

These requirements are similar to those that would be used to defend a product patent in a legal conflict. In a real research and development laboratory, the notebooks would be bound and all writing in ink. Errors are not erased but crossed out with a single line. This is probably a bit much for students. However, they need to get in the habit of providing good documentation of their work. I have attached a template for a notebook page in Microsoft word. They can either use this page or generate a similar page and keep them in a loose-leaf binder. This binder is their project portfolio.

Maintain a laboratory notebook every day

- Start each day and design step on a new page
- Number and date each page
- You and a witness should initial the bottom of each page
- Write down what you did (pictures and drawings help)
- Write down any decisions that were made

Memos

Memos are *short* documents (1-2 pages maximum) to bring the reader up to date

I suggest that students write weekly memos to Dr. Fleam to act as progress reports. The goal of these memos is to (1) make the students plan their progress, (2) keep the students on track, (3) make them aware when they deviate from their plan. I tell the students that their grade for the memos will reflect the quality of the memo and their ability to meet their plans or justify the deviation from their plans. In practice, I recommend that you let them modify their schedules at will as long as the final completion date does not move.

Memos should contain...

- What you planned (1 paragraph)
- What you actually did (and why it differs from what you planned) (1-2 paragraphs)
- What you are going to do next (1 paragraph)

I emphasize that this is not a case where longer is better. Each of the section lengths is a maximum, not a minimum.

The Design Report

The design report is the final project report. In the scenario, the lab report will be presented to Dr. Fleam to be used for the creation of new products. Emphasize that this report is a formal report and that appearance counts. The report should contain the following elements:

Write up a design report containing

- A short cover letter
- A one page summary of your design
- A table of contents
- A background section discussing the problem and what products already exist
- A description of your goals and specifications
- Detailed documentation of your design, including descriptions of the product, how it was made and how it is used
- An appendix
    - A list of all its components, where they came from, and what they cost

- Drawings of all of the parts of your design
- An instruction sheet describing how to use your product
- A copy of the evaluation and improvement information from stage 6
- Copies of the pages in your lab notebook

What is good design?

Functionality – *Does the device perform the desired function? Does it fit inside the cast? Does it provide relief from the itch?*

Quality – *Is the device of an appropriate quality? Does it look good? Can you produce it repeatable? Will it last as long as the user is in the cast?*

Safety – *Is the device safe to use? This includes use in unexpected way or by someone who is poorly trained? Ask your students to consider the items in the classroom that they have used in an unexpected way (e.g. using a pencil to scratch an itch that they cannot reach). Children possess most of the broken arms. How would these factors alter their design?*

Ergonomics (user friendly). – *Does the device fit into the available space? Is it easy to hold and use? Is it comfortable to use?*

Appearance – *Does it look attractive? Does it look well made? Would you want one?*

Environmental Considerations – *Is you device made using an environmentally safe process? Everything that you purchase will one day be thrown away. Is your device recyclable?*

Societally Appropriate – *Does the design match the audience? A design that is appropriate for a 5 year old may look silly when used by a grandmother. A design for vegetarians shouldn't have a leather strap.*

Economics – *Can people afford to buy it? Can we afford to build it? Can we afford to sell it for a reasonable price and still make a profit?*

Manufacturability and Maintainability – *Can we build it with the equipment and materials that are available? Can it be fixed if it breaks?*

The 7-Stage Design Process: The 7 Ds of Design

- Stage 1: Definition and specification of the product
- Stage 2: Data acquisition and analysis
- Stage 3: Discussion of solutions
- Stage 4: Development and testing of the models
- Stage 5: Decide on your design
- Stage 6: Design implementation
- Stage 7: Do it better next time

Stage 1: Definition and specification of the product

Develop a product that improves life for people with broken arms

You could …

- Develop a new kind of cast
- Improve an existing kind of cast
- Develop a product that makes living with a cast easier
- Develop a product that makes a cast look better

Define the product

- What problem are you going to fix?
- What does the product do?
- How does it perform its function?
- How long does it have to last?

The product specifications

- What are the product's...
- Size?
- Shape?
- Function?
- Durability?
- Maximum Cost?

Stage 2: Data Acquisition and Analysis

Before engineers begin to design, they learn what has already been done. This background research is one source for ideas. It is also important to avoid conflicting with someone else's design. Students have a range of resources that they can use to get information for their design.

This stage will answer the following questions

- What does your product need to do?
- What do existing products do?
- What do they look like?
- How do they work?
- What are they made of ?
- How do they meet your specifications?

Where can students find information?

- Library
    - Books
    - Research and Trade Journals
    - Newspapers
    - Government publications
    - Textbooks
- On-line – *Be sure to inform students of the difference between a reliable web source and an unreliable source. The sources listed below are generally reliable, though a manufacturer is going to provide information that is slanted in their favor.*
    - Patent search
    - Medical Associations

- Governmental Agencies
- Manufacturers

- People
  - Health Professionals – *These individuals have experience with applying casts. They are a good source of problems with applying a cast. In addition, they will help the students determine the properties of a good cast.*
    - Nurses
    - Doctors
    - Surgeons
  - Patients – *Ask if a student in the class has ever worn a cast. What did they dislike about it? What would they like to see improved?*
    - Yourself
    - Friends
    - Family

You will want to adapt these slides to match your available resources

Stage 3: Discussion

Brain Storming is a good way to create new designs. Some of the rules for brainstorming are below:

Part I - Brainstorming

- Think outside the box
- Invite diverse members to help generate ideas – *(e.g. women, men, friends, engineers, doctors, nurses)*
- Write down every idea that comes to mind – *at this stage there are no bad ideas. Student will choose the best ideas later, but negative response by their peers tend to inhibit students*
- You should have 10 - 20 potential ideas – *This is a difficult challenge for students. They tend to get hung up on a single idea. Press them to come up with a minimum of 3 ideas per group member and make them write them down.*
- Don't pass judgment on ideas or people

Part II - Sifting the ideas

- Combine all of the lists
- Examine the list to eliminate duplicates
- Clarify each item on the list
- Evaluate each of the ideas
- Pick the best 3-5 ideas

Part III - Refining the best ideas

- Common sense
- Manufacturability – *Can the students complete the design in the available time?*
- Economic analysis – *Can we afford to do it*
- Engineering analysis of product – *Is the design feasible? Is it strong enough, fast enough,*
- Avoiding existing designs and patents
- You may need to eliminate or add solutions at this stage

Stage 4: Develop and test models

Engineers build models to see if their designs will work as well (hopefully better) as the plan. Not all models are physical. In fact, more and more of the models are computer generated.

Teachers should provide some poster-board and large sheets of paper for the students to build mock-ups

Build quick and dirty models of 2-3 best choices – *Again, the students will want to focus on a single design. This process helps them to realize that there are many good design opportunities and prevents them from becoming trapped in a single idea, if it doesn't pan out. You will also need to emphasize that these models are "quick and dirty." They don't need to be (and probably shouldn't be) pretty. They just need to provide enough information for problems to be identified and for decisions to be made.*

Models can include
- Mathematical models
- Computer models
- Scale models and mock-ups
- Diagrams and graphs

At this stage in the design process, the students will pick one of the designs to continue to completion. Start by having the students look down the list of the qualities of good design and make a list of the things that they consider important. Some of these are:

Things to consider in evaluating your models
- Durability (will it last under the conditions that you will use it, e.g. rain, playing, etc.)
- Is it easy to use/put on?
- Strength
- Environmental
- Quality consistency (can you make more than 1)
- Safety
- Consumer appeal (does it look good?)

This list will act as the foundation for the decision table.

Stage 5: Decision

Make a decision table – *Take the list generated above and assign a number of points to each item on the list. A larger the number of points means that that item is more important. Have the group evaluate each design (not each model – the final product will be better than the quick and dirty model) and assign points for each item on their list. The highest point item is the one that is finalized.*

The steps in creating a decision table are:
1. List your product specifications

2. Add any other important criteria from the list of “qualities of good design” to this list
3. Put them in order of importance from most important to least important
4. Assign a point value to each item on the list
5. Evaluate each product and assign a number of points for item 1 on the list
6. Repeat for item 2 and until you have completed your list
7. Add up the points for each item to choose the best design

An Example Decision Table

Criterion	*Points*	*Choice 1*	*Choice 2*	*Choice 3*
Cost	*25*			
Production	*20*			
Appearance	*30*			
Safety	*15*			
Legal	*10*			
Total	*100*			

Stage 6: Design Implementation

Finalize the design

- Make any final improvements to the best design (don’t be afraid to take ideas from your other designs)
- Determine final color, appearance, etc.
- Build your final version of the design (this one should look nice)

Stage 6: Do It Better

Engineering design is not a single process. Virtually every item that we see has gone through many design cycles. In each cycle, the design is improved and the design process gets better. Your students will need to reflect on the process that they have just completed. They will need to reflect on each of the following three categories

Evaluation of the Design

- People
- Process
- Product

Emphasize that the goal of this final stage of the design is improvement, not whining or recrimination. One way to do this is to require that they generate a solution/recommendation for each problem that they identify. For each of the 3 categories they should ask these questions

- What did we do right? (How do we do it again)
- What did we do wrong? (How do we stop from making the same mistake again)
- Examining the above questions, how can we improve what we did?