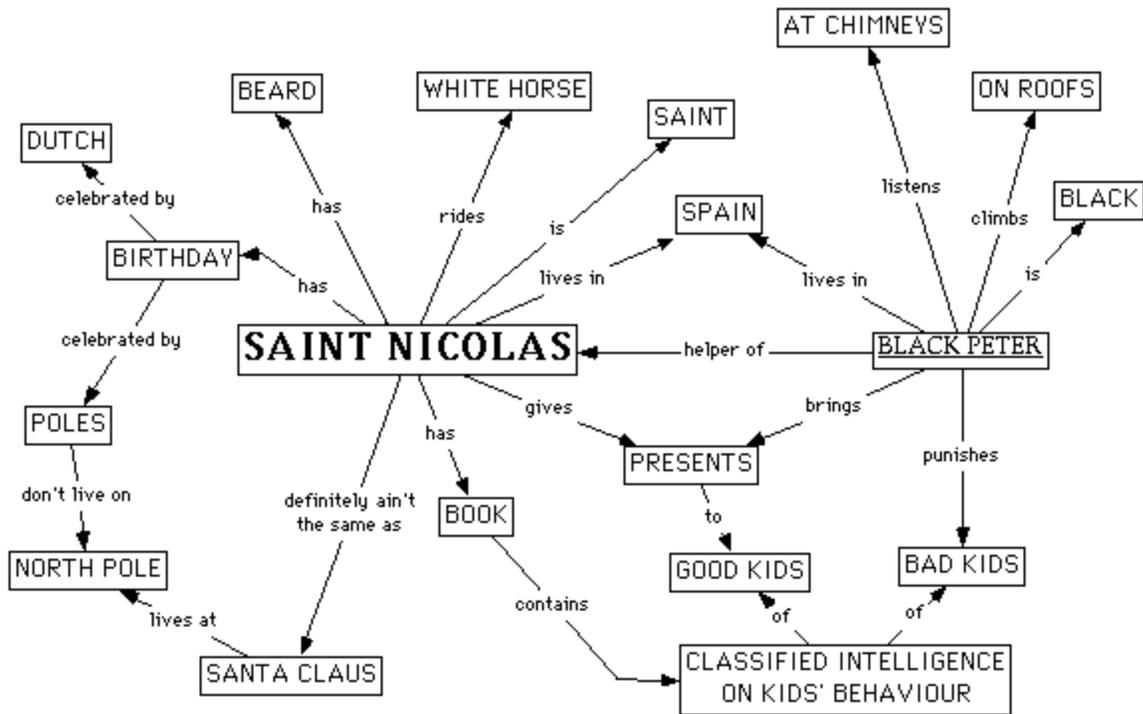


## Chapter 2 (Fundamental Design Tools) Material:

1. Do a web search with the search term “Brainstorming”. Evaluate several of the sites, try some of the software available and report on the usefulness of the program.
  - Many of the web searches in this text may appear to the student to be of little value. The goal of many of these exercises is to guarantee that they are familiar with a variety of terms that they might otherwise have to learn much later in life.
2. Do a web search with the term concept map. Find and explore one or more example concept maps.
  - The student search should appear to be more than superficial and should incorporate information from the chapter and lectures.

For example: A web search of concept maps was performed using Google as the search engine. The first hit produced a web site that defined concept mapping and provided the example shown below:



The concept map graphically represents information on Saint Nicolas. It shows descriptions of and relationships between the subject's physical appearance, frequent activities, location, occupation, and personal contacts, as well as terms commonly associated with the subject. Some of the concepts are interrelated; for example, Saint Nicolas' birthday is celebrated by the Poles. Saint Nicolas is also not the same as Santa

Claus, who lives at the North Pole. The author makes the connection that the Poles do not live at the North Pole. The concept map was found at *The Concept Mapping Homepage* ([http://users.edte.utwente.nl/lanzing/cm\\_home.htm](http://users.edte.utwente.nl/lanzing/cm_home.htm)).

3. Draw a process diagram for the process of taking hamburger meat, grinding it, then flattening it and cutting out presized hamburger patties. The meat that is in between the patties is reinserted into the process just after the incoming meat is ground. What is wrong with this process? If necessary do a web search to answer this question.

-- The answer does not have to be complicated, but the diagram type should be correct WITH the arrows and such. The student must realize the flaw in the process is the passing back of old meat into the process which can contaminate the entire system. Students could possibly benefit from searching the FDA web site on proper handling techniques: A good student search will find the name of the hamburger chain that did exactly this and caused a series of deaths due to food poisoning.

The requisite steps and processes are as follows:

Process step	Operation
Transport meat to grinder	Transport
Place meat in grinder, grind	Operate
Transport meat to flattener	Transport
Flatten meat	Operate
Transport meat to cutter	Transport
Cut meat into patties	Operate
Store patties	Store
Add leftover meat to meat in transit to flattener	Transport

4. Visit the web site [www.jellybelly.com](http://www.jellybelly.com) and find their process listing. Do a flowchart of this process, specifically identifying delays. Discuss means to speed up this process. Extra credit, request that samples be sent to your instructor.

Students should use a flowchart (not a process diagram) to work out this problem. One of the major items to not is that there are several extensive “delays” that should be discussed.

5. Visit any web site that has an example concept map that is of interest to you, print out the map, and comment on the value of it.
  - Fairly straightforward, expect a variety of answers, some of which may be useful teaching tools in the next term.
6. Pick two design terms or terms relating to a project you have worked on. Pick two different search engines and search on these two terms. What are the differences in yield? Would you recommend one search engine over the other? Why?

- There are far different yields, for example, between Google and Scholar Google, hopefully the students have noted this by now.

7. Do a web search on the term Biomimetics, find a good example of this as applied to a design problem, print it out and discuss it.

From Wikipedia, “**Bionics** (also known as **biomimetics**, **biognosis**, **biomimicry**, or **bionical creativity engineering**) is the application of methods and systems found in nature to the study and design of engineering systems and modern technology.” Student examples will range considerably, from sonar to paint, etc.

8. Generate a simple process chart for the process of brushing teeth.

Charts should include the steps of picking up the toothbrush, loading toothpaste, brushing, cleaning, etc. Charts will vary somewhat, a reasonable effort is expected.

9. Generate a flow chart for the process of obtaining breakfast. Be sure to indicate delays and make suggestions to decrease same.

These charts will vary considerably, dependent on the life style of the individual student. A reasonable effort is expected.

10. Generate a simple selection diagram to determine whom you will date for a formal dance.

Any reasonable attempt will do here, as there are too many potential variables.

11. Generate an evaluation chart to assist you in the determination between camping in the mountains or going to the beach for your vacation this year.

Reasonable attempts, again., desires v. wants, rankings needed.

12. Generate a simple QFD chart for the selection of an automobile.

This too will be student dependent, but generally should include such items as quality = inexpensive, speedy, economical, eye-catching, reliable, good looking, etc. and functions such as transport, crashworthiness, trunk space, , etc.

13. Generate a QFD diagram to help design a better device for closure of an atrial septal defect.

Qualities should include easy to install, safe, low cost. Functions should include closes atrial defect, may include re-absorbable, may include non-thrombogenic, etc.

14. A problem that arose in the early use of long-barreled cannons was that they “wilted” during repeated use due to heating and uneven cooling, especially during rainstorms. Use brainstorming with one or two friends to help solve this problem. Reference the TRIZ contradiction matrix and attempt to find a solution. Document your choices.

Student responses here too will vary. The important item for them to consider is that – although the cannon is symmetric, the effect of the environment is asymmetric. The student should consider rotating the cannon in order to even out the effect of the environment. (Shape, item 12, weight of non-moving object, item 2, length of non-moving object, item 4, temperature, item 17, can all be called up.)

Most of the above exercises can be used as teaching examples & the best responses recycled into lecture material in ensuing years.

The meat patty homework (3) is an excellent teaching example – for example – the discussion may be had regarding the use of square patties (a la Krystal) that do not necessitate the recycling of hamburger meat to “use it all”. One can also look at the dynamics of bacterial growth and give some consideration to how quickly one needs to stop ground meat from being re-cycled.

This chapter also lends itself to the generation of brainstorming sessions. One I used almost every year involved how to clean ear wax out of an uncooperative child.

### Chapter 3 (Design Management, Documentation, and Reporting) Material:

1. Take the material written just above on the rules for a poster session; generate a PowerPoint presentation that conveys the same thoughts in a more vital fashion.

Students should be given credit for a reasonable attempt here.

2. For the material on PowerPoint presentations, demonstrate several of the points made using a PowerPoint presentation.

Reasonable attempt count here too, but expect some surprises – such as unreadable slides, garish slides, etc.

3. Perform a web search for optical character recognition (OCR). Comment on the range of uses for this method of data entry. Comment on some of the disadvantages of this method.

The main drawback to OCR (according to author King) is that many personnel with access to Xerox machines do not properly insert data forms to be used in later OCR steps, resulting in lost time or data.

4. Draft a design for a computer method that would contain the relevant information needed to catalog equipment used in a medium sized biomedical engineering department. At what point would you consider the use of Access over Excel?

Data fields should include such items as device name, manufacturer, serial number, preventive maintenance data entries, location for use, ownership, etc. If there is any chance that the number of entries will exceed 32,000, an access database should be immediately considered.

5. You are in charge of developing a database for a drop-in clinic for a medium sized city. What would be some of the key parameters you would need to enter on every patient? Discuss this briefly.

- Each new patient to the clinic should be assigned some sort of UNIQUE identification number. Basic information including address, phone numbers, social security number, date of birth, and insurance information should be entered into a table tagged with the id number. This table could be linked through the id number to a table containing the patient's medical history which would include any allergies, existing conditions, current medications, previous illnesses, injuries, and operations, family medical history, and risk factors. Both of these tables should also be identified by the date created and the date of the most recent update. These tables should also link to dated tables containing information about each particular case. Important information to be entered here includes symptoms, tests conducted, diagnosis, prescribed medication, other recommended treatment, and follow-up visits. Be sure to note to the students that social security number or name is not a unique identifier!

6. Perform a web search using the term “teleforms”, comment on the uses outlined.

- This exercise will be class and search engine dependent. The bottom line is that it is a optical character system useful for data entry. (See also 3 above.)

7. Construct a “design team “exercise during or after class to tackle a design exercise. Reporting will be done orally by one of the team members. Members must take one of the following roles: Marketing, Manufacturing/distribution, Legal/Safety, Engineering, or team leader, members are responsible for assuming their “roles” on the design team. Design topics could include any one of the following:

- Design a device to detect SIDS in an infant.
- Design an automated EEG electrode placement system.
- Design a device to track Alzheimer’s patient’s locations.
- Design a system to track asthmatics location and sample the environment for noxious stimuli.
- Design a head restraint system for race car drivers
- Design a pain clinic database.
- Design a system to quantify male or female arousal in an MRI machine.
- ...any other design suggested by your instructor.

Most students should find the role playing of value in the development of any of the above items. Be sure to ensure that the teams understand the who/what/why/where/when material involved in each design effort. This can be a useful one class or 1-2 week exercise, dependent on your interests as an instructor. I generally found that it was a good one-class exercise if the students could “get into” the roles. The topics presented can also be used for a 1-2 week design exercise prior to the class dismissing for the remainder of the design project normally required here.

Instructors that consider the use of access or other databases of value should consider exposing their students to lectures on Access or other programs. Assuming author King’s website still exists, see, for example, [http://research.vuse.vanderbilt.edu/king/Paul\\_King\\_Lecture.ppt](http://research.vuse.vanderbilt.edu/king/Paul_King_Lecture.ppt) for an example lecture (given by Dr Paul Harris) ...

A typical homework example given by DR. King follows:

#### BME 272 Fall 10 Access Homework, 20 Points

Assigned October 7, 2010

Due : October 19, 2010

#### ACCESS ASSIGNMENT

Dr. Freeman (Dr. Fre) wishes to plan his summer vacation schedule including family outings and various medical conferences around the world. In order to do so, he must obtain a comprehensive overview of all his surgical procedures dating 3/99-9/99 including the times of each. For the more risky surgical procedures (Sur Proc Related Risk > 1), he needs more time to prepare. He must also notify anesthesiology well ahead of time for patients “at risk” for their procedure (ASA Class > 2,) giving them adequate preparation time as well. As you might

suppose, Dr. Freeman has also requested the specific procedures as well as **relevant** information as to why the patient would be considered “at risk”.

Go to <http://research.vuse.vanderbilt.edu/King/seniordesign.zip> and download the patient database. Create a query to obtain all the relevant information needed for Dr. Freeman’s assessment.

- a.) How many cases does Dr. Freeman have to consider over this time period? (include cases that do not have a scheduled date)
- b.) How many of these patients are undergoing a risky surgical procedure?
- c.) How many of these patients are considered “at risk” for the anesthesiologist’s procedure?
  1. From the info you acquired, speculate the reasons why these patients are considered at risk. *Be specific.*
- d.) Dr. Freeman was hoping to take his family to Disney World this summer. He has discount airlines tickets and free passes for dates 6/9/99-6/17/99. Is this feasible? Why/why not?
- e.) The American Medical Association Conference is in Honolulu, HA, 5/16/99-5/19/99. Should Dr. Freeman plan to attend-why/why not?

Finally, generate a report containing all the **relevant** information for Dr. Freeman’s assessment of “at risk” patients so that he can go ahead & notify anesthesiology. (*Hint : remember, ASA Class > 2*)

Print this out and turn it in with answers to the following info above.

You may work in groups of up to three members on this assignment, be sure to put all names on the material posted to Oak. Post only once please.

#### Chapter 4 (Product Definition) Material:

1. Do a web search on QFD, report the number and geographical distribution of the information found, comment on these results.

At the time of this writing, most QFD work was being done in Japan, the US, and in Europe.

2. QFD can be used for technical as well as social system development. Find and report on an example of an improved clinic or other system based on QFD principles.

Result will vary, dependent on the search engine and terms used.

3. A related technique is called six-sigma. Do a web search to define this term, then comment on its relationship with QFD.

Six-sigma is primarily a process to systematically remove defects in a process. No-defects could be a quality item in QFD work.

4. Find and report on any QFD application to a technical problem.

Result will vary, dependent on the search engine and terms used.

5. Develop the first level QFD diagram for your next car purchase.

Quality items should be obvious (good looks, comfortable, etc.), functions too (transport, etc..)

6. Develop the second level QFD for the car purchase.

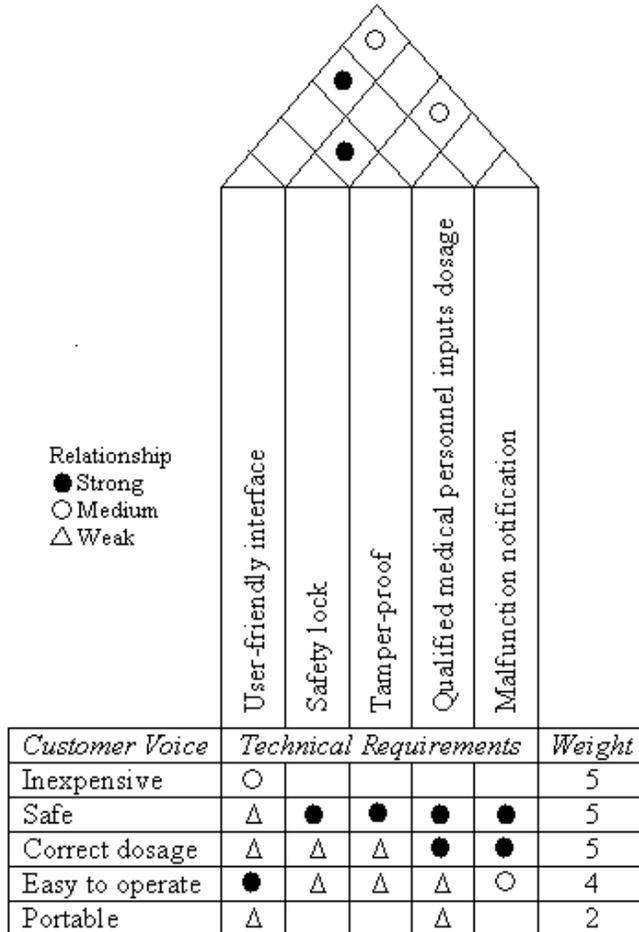
Concept requirements could include: good looks, riding comfort, miles per gallon rating, price, reliability, estimated service costs. Design concepts could include: interior design, lumbar support for the seats, engine design, weight of the car, robotic versus human manufacturing. The design concepts would then need to be rated with regard to the concept requirements.

7. Develop the third level QFD for the car purchase

Once the best concept alternative is chosen, each component in the selected design concept is examined to determine its critical part requirements. For the interior design for example, the size of the steering wheel must be established. The range of the adjustable movement of the steering wheel must be established. The material composition of the steering wheel must be established. The force of the air bag deployment must be established to ensure safety.

8.. You are an employee of Sleep-EZ Inc. You are charged with the development of an inexpensive anesthesia machine for use in third world countries. Develop a 3-level QFD matrix for this task.

- Answers will vary considerably dependent on the software used (preferable) and the student's understanding of the process of anesthesia. A few software packages have trial versions that may be downloaded. An example mid-level answer may be seen below:



9 Develop a set of requirements for the above anesthesia machine.

Requirements could include: operable on various power sources, battery backup, include one vaporizer on the machine, limit the number of monitors to those essential for safety, operable in various temperature and humidity ranges, use of materials that will keep the cost of the machine low, transportable, operable at various altitudes, use of international symbols rather than text.

## Chapter 5 (Product Documentation) Material:

1. Write a one page business proposal for your design project. Rough out a product specification page and design specification page if applicable.

Student dependent answers.

2. You are going into competition with Johnson and Johnson; you plan to capture 30% of the market for Band-Aids. Do the needed web search to determine your market potential in terms of the US market.

This might take some digging, but if the student hits upon band-aid.com, they will find that J&J had sold 100 Billion by the year 2001, they were originally developed in 1920. With any reasonable guesswork, the student should estimate that they would need to produce .3\*2 Billion or so bandages!

3. The web site medicaldesignonline.com has daily columns discussing new medical developments. Go to this web site (or a related one) and peruse the industry news section. For one of the recent developments listed, discuss and document the market need. Identify what was obtained from this site versus what you obtain from other site searches.

- Students need to be aware that there are a number of web sites that contain useful medical device information. Responses should reflect class and prior knowledge about a particular subject.

4. Improper record keeping and other poor practices have bankrupted several medically related firms. Do a web or library search to find such a case. Briefly discuss the case.

Most students should come across "How FDA regulation and Injury Litigation Cripple the Medical Device Industry" by Charles Homsy. A.H.Robbins (Dalkon Shield), Vitek, Novamed, and Dow Corning are all mentioned. Google Scholar is probably the best search engine for this task.

5. You are assigned to investigate the consequences of prostectomy. Identify the current market for this operation and the consequences of the operation. Identify a need for improvement relating to your observations.

A web search should turn up over 20,000 entries, some of which will discuss quality of life issues (recovery time, lack of urinary control, loss of sexual function, etc.)

6. Do a web search using the term "medical device ". Detail how many hits are really consulting firms that assist in the structuring of a business proposal or product specification. Print out documentation on two or three of these companies and discuss what the product really is in terms of this chapter. The use of a good search engine (such as Go Network) is recommended, most of the single search engines are not powerful enough.

Results are student dependent.

7. There are a few web sites that specialize in determining the market for devices or treatments that target a complex of consequences of lung disease or the like. Most charge a high fee for identifying opportunities for entrepreneurship in the field. Find such a site, document it, and discuss the perceived value of the information.

Students should be made aware that much medical information can be obtained, but at a high cost. Some firms even charge for paper copies of freely available FDA regulations!

## Chapter 6 (Product Development) Material:

1. From the QFD developed for the anesthesia machine in Chapter 4, develop a list of requirements for the device.

### Examples:

The anesthesia machine shall operate according to specification in a temperature range of 45 - 65°C.

The anesthesia machine shall meet the requirements for electromagnetic compatibility of IEC 601-1-2.

The anesthesia machine shall contain a pulse oximeter.

The anesthesia machine shall operate when connected to 120V, 200V and 240V power sources.

The anesthesia machine shall contain a backup battery capable of 3 hours of operation

2. Develop a list of design inputs for the anesthesia machine above, based on the requirements.

### Examples:

Operating temperature range of 45 - 65°C

Storage temperature range of -40 - 75°C

Operating humidity range of 5 – 95% relative humidity

Input power range of 120V +/- 10 V @ 60Hz

3. Develop a list of risks involved in the use of the anesthesia machine.

### Examples:

The machine overheats due to extremes in ambient temperature.

Power sources are unstable and may affect the functioning of the machine.