The Development of a Hematology Unit: A Case Study in the New Products Program Design Methodology

by

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Abstract

The New Products Program (NPP) is a new program at the Massachusetts Institute of Technology (MIT) linking academia and industry for mutual benefit. A company sponsors a team of MIT students and faculty to design and develop a working prototype of a new commercial product. This relationship results in many benefits for all parties involved.

The current design process being applied by the NPP product development team is basic concurrent engineering, including the use of a multifunctional team and Quality Function Deployment (QFD).

The design methodology currently being used by the NPP is thoroughly analyzed, based on one of the NPP projects, the development of a commercial hematology unit for Becton-Dickinson and Company. The strengths and weaknesses of the design process are emphasized. Suggestions for an improved project organization and design process are given. These suggestions are based on other documented experiences and literature on design methodology. Detailed attention is focused on the design phase of the Becton-Dickinson project.

Thesis Supervisor: Professor Woodie C. Flowers

Title: Pappalardo Professor of Mechanical Engineering
Director, New Products Program

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I would like offer my sincere thanks to the following people for their help and support throughout my life and most especially, throughout my involvement with the Becton-Dickinson project:

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To my brothers and sister who have always shown me the way and paved it for me. My accomplishments are fruit of your work and constant example.

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To my roommates, Hana, Paul, and Henrik who tolerated me throughout many tough times.

To Melanie, who has always been patiently there for me, listening, supporting, and sharing all my joy, sadness, failures, accomplishments, boredom and excitement.

And, to the Almighty, whose faith in me is never-ending.

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Chapter 1. Introduction

"Wisdom is the ability of the brain to accept useful information, learn from it and act intelligently on it."
- Dudley Lynch and Paul Kordis

In this thesis I analyze the New Products Program (NPP) development process for a new products based on my experience with the Becton-Dickinson project in developing a blood analyzer. After the completion of a project, members of a product development team meet with the various people from the different departments that were involved with the project and analyze the problems and successes of the project. In this manner, the same mistakes can be avoided and the successful techniques can be repeated in the next projects. This critical and very constructive analysis is sometimes referred to as a post-mortem.

The main idea behind a post-mortem is that everyone should learn from their own and other people's successes or mistakes. The post-mortem is a continuous improvement technique which identifies the errors, delays, mismanagement, and all other problems as well as the successes associated with the project and tries to determine their root causes. Then, the review team attempts to implement solutions to the problems so that a great majority of them will not be repeated in subsequent development projects. The post-mortem is the search of useful information and the application of that information for future benefit. This thesis is a post-mortem of the New Products Program- Becton-Dickinson project.

Examples of the benefits reaped by post-mortems are numerous. At IBM, after the main problems are identified, a database is produced that contains the problems that were faced by a particular project and the solutions to those problems. The database can be easily accessed by merely typing keywords into a computer. Such action has reduced error by half while in other projects it sped the schedule by 16 weeks. At Motorola, there has been seven-figure savings due to the implementation of post-mortem after one project. And at Xerox, this activity is so important it is called a presidential review since even the president becomes personally involved (Zangwill, 1993).

A post-mortem may take many forms. It can be an iterative process of improvement similar to the PDCA cycle of Total Quality Management (TQM). PDCA is an acronym for Plan, Do, Check, and Act. It was first introduced into the Japanese Industry by W.E. Deming. *Plan* is the determination and identification of the key problems with the current process or activities. *Do* is the implementation of the plan. *Check* confirms that the plan will improve the current process or activity. *Act* applies the specific changes necessary for improvement, then documents and applies the new improved process or activity (Shiba et al, 1993). The application of the PDCA cycle leads to higher quality, it is improvement in an incremental fashion (see Figure 1.0).

It is important to note that the knowledge gained from a thorough review of a project can be best applied at the beginning of a new project. Formal reviews should be held at the kick-off of a new project to familiarize with the potential problems that might arise, and to implement the solutions to those problems. These are the *check* and *act* stages of PDCA.

A newly-formed NPP team could find it useful to read and discuss this thesis. Since every team in the NPP is new for each project, the team members have no knowledge gained from previous experience in such a program. The only sources of information for the new team members are the previous NPP students and professors, and the theses written by these students. As of today, no thesis other than this one concentrates on a post-mortem of a New Products Program project. The information in this thesis could be extremely useful and serve as guidelines to avoid errors and repeat successes in the design and development of a product in the next NPP project.

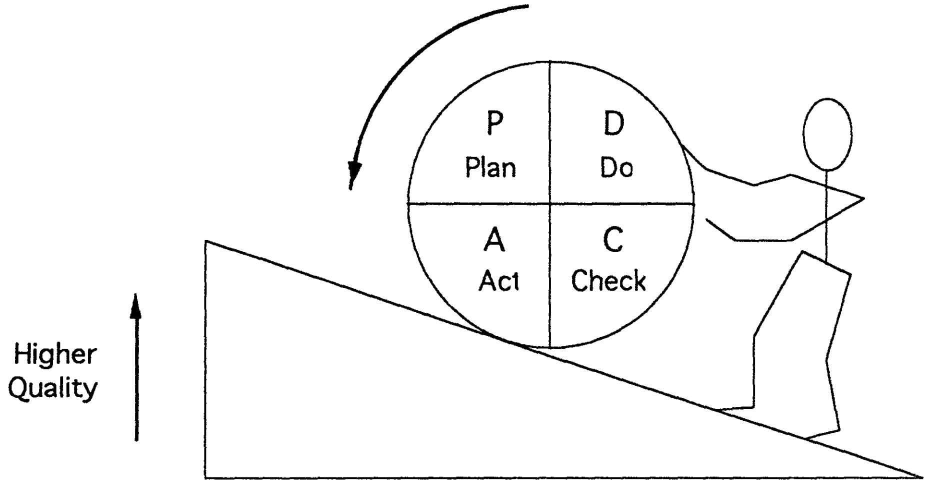


Figure 1.0. The PDCA Cycle (Shiba et al, 1993)

The most important characteristic in identifying a problem to improve it is weakness orientation. Weakness orientation is an outlook into a problem with intent of searching for its root causes. On the other hand, strength orientation does not identify the problems. Instead it improves on the performance achieved through the previous process. Improvement in this case can be limited by the capacity of the process itself and the best solution might never be reached. This thesis will use both the weakness and strength orientation approach. It will be governed by the following characteristics:

- an objective approach: a search for facts and not opinions;
- an analysis of the process and not the result; the result is merely the effect of the process; good results will be used as identification of possible strengths in the process and poor results will be used to identify weakness in the process;
- and, a search for root causes followed by suggestions of solutions for improvement; the root causes must be determined before trying to determine solutions for improvement. In this manner no problems are skipped without being first analyzed.

This thesis is more than a documentation of my work in the NPP-Becton-Dickinson project. It is the documentation of my work in light of the successes and failures throughout the project, such that, future NPP projects can learn from this experience and further improve its product development process. In Chapter 3, I critically review some of the design process steps in the Becton-Dickinson project. Many of these steps had a strong impact on the outcome of Walkaway, and in future NPP projects, these steps can be imitated or improved for even greater success. Particular attention should be given to Chapters 4 and 5 where I propose improvements to the NPP design process, based on my experience in the Becton-Dickinson project.

Section 1.1 - The New Products Program

The New Products Program (NPP) was recently created at Massachusetts Institute of Technology (MIT) in an effort to link academia and industry for a mutual benefit. The NPP, as its name suggests, agrees to design and develop a new commercial product for a sponsoring company. The project typically has a duration of two years, but may vary from project to project. The cost to the sponsoring company is typically $500,000, but also changes according to the magnitude, nature, and duration of the particular project.

In the U.S. there is a gap between basic research and scaled production (Preston, 1993). The NPP bridges this gap by providing the necessary efforts in transferring basic technologies into commercial products (see Figure 1.1). The NPP extends the range of MIT activities beyond just technology development and include both bench and pilot phases.

The benefits to the NPP members and the company are many. The group of students and professors involved in such a program experience a real-world application of design and development. They become very familiar with the design process and the many aspects involved in developing a commercial product. This practical experience is complimentary to the theoretical knowledge the students acquire in the classroom. Many other experiences in a NPP project, such as leadership and team work, are not taught in a classroom, and becomes extremely invaluable to the students. Moreover, the money given to fund the project also helps pay for the students' tuition and stipend. With the high cost of tuition and living expenses at MIT, and the limited amount of research and teaching assistant positions available, the NPP gives many students an opportunity to attend MIT at no cost.

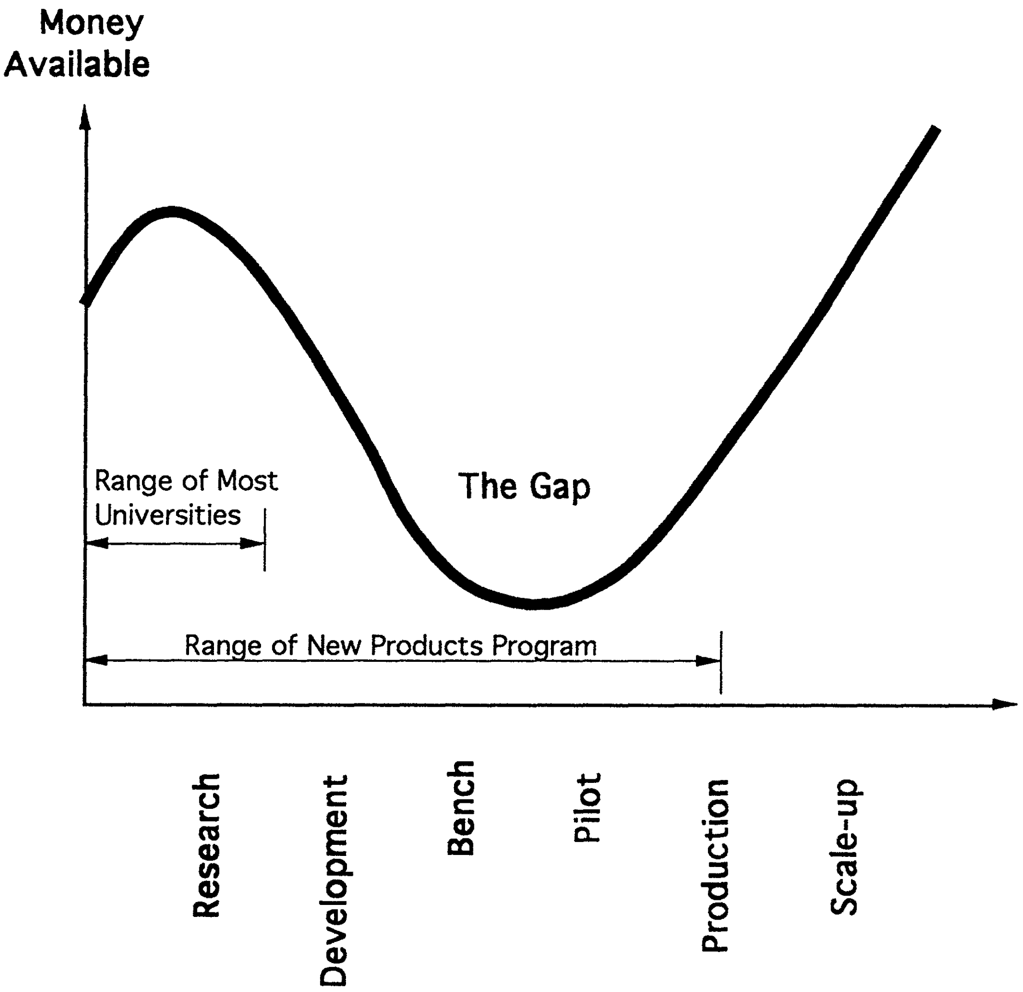


Figure 1.1. Funding the Gap (Preston, 1993)

The benefits for the sponsoring company are just as numerous. The company receives a working prototype for a relatively small cost and in a short time. Typically, in a large company, the cycle time for the development of a new product range from 3 to 6 years. The NPP delivers in 2 years. Also, the cost to most companies for the development of a new product is over $2 million. The company also taps into a large resource of information and state-of-the-art technology. When faced with a problem, students in the NPP team can ask other MIT professors for guidance. These students usually get this "consulting time" at no cost to the company. All this translates into benefits to the company. In a broader scope, the NPP generates leaders in product development, which ultimately benefits society.

Section 1.1.1. - The Organization and Strategy of the NPP

The organization of a NPP project begins with a team leader, usually a MIT professor. To aid the students in the different fields throughout the project, a few professors are also hired as part of the team. These can include professors in Electrical Engineering, Computer Science, Marketing, Mechanical engineering or other fields depending on the project. The core of the NPP team comprises of a group of Masters and Ph.D. level graduate students, ranging in number from 3 to 5, and a couple undergraduate students. This core team is composed of students in different fields, all of which are important to the development of the new product. The number of members in the team may vary depending on the complexity of the project.

The students and professors are hired in a part-time basis, as they have to balance work and academics. Each student is expected to work 20 hours per week in the project. For professors, this amount of time is smaller since their participation in the project is not as intense in a daily basis. However, as could be expected, the students in the project spend more time in the project. It is important to note that many companies have a cycle time of 3 or more years with full-time employees working on a project. The NPP only has students working part-time, which extrapolating into full-time hours the NPP cycle time is just over one year.

The design process utilized in the NPP is basic concurrent engineering. Basic concurrent engineering is a significant improvement in game plan and teamwork relative to the traditional serial design process. The better game plan is the concurrent process, reinforced by emphasis on quality, cost, delivery, and customer satisfaction. This emphasis is achieved through the use of Quality Function Deployment (QFD). Better teamwork comes from the use of a multifunctional team.

As stated above, the NPP was not created only to produce a working prototype for a company. The NPP is also a learning experience for all those involved, especially the students. Although the students agree to design and develop a product, it is not fair to demand that the students perform a perfect job, particularly in regards to following a design process. To most students involved in the NPP, the project is their first real-world experience with the design and development of a commercial product. Although many design classes at MIT attempt to simulate the process related to product development, most of these attempts are never able to imitate a real product development project in its entirety. In this thesis, although I point out many imperfections in the design process of the Becton-Dickinson project, my intentions are not to criticize the work done in this project, but to emphasize the areas that can be improved for future NPP projects.

Section 1.2 - The Becton-Dickinson Project

Together with another project, the Becton-Dickinson project was the first NPP venture. The Primary Care Diagnostics division of Becton-Dickinson and Company sponsored a NPP project to develop the Walkaway, a fully automated blood analyzer based on the Quantitative Buffy Coat (QBC) technology. The project comprised of two phases including: a *conceptual phase* where the product development team did market studies and concept generation, and determined the final concept of the Walkaway; and a *design phase* where the concept for the Walkaway was transformed into layout drawings and into an alpha prototype. My involvement with the Becton-Dickinson project began with the design phase and this thesis will concentrate (but not limit itself) in analyzing the strengths and weaknesses within that phase. Table 1.1 and 1.2 lists the core team for each phase of the Becton-Dickinson project.

The design phase of the Becton-Dickinson project can be divided into two segments: first prototype and alpha prototype. The first prototype aimed at testing the functionality of all the subsystems and showing its overall functional layout. The alpha prototype aimed at not only showing all the functions of the Walkaway, but also demonstrating the true components of the machine, including final concept, shape and layout. Although the first prototype did not resemble much of a commercial product, it was a very important prototype for the product development team (PDT). It finally put the many subsystems together to form a blood analyzer, the Walkaway. This visual and functional "tool" was a foundation on which a better prototype could be built.

Table 1.1 - The Core Team for the First Prototype

Amy Battles - Mechanical Engineering Graduate Student
Laura Edwards - Electrical Engineering Graduate Student
Ben Linder - Mechanical Engineering Graduate Student
Andres Pieczanski - Mechanical Engineering Graduate Student
John Sieh - Mechanical Engineering Graduate Student
Ming Wu - Mechanical Engineering Undergraduate Student
Brad Thomas - Becton-Dickinson Engineer
Dave Otten - Electrical Engineering Professor
Eric Vaaler - Mechanical Engineer
Woodie Flowers - Mechanical Engineering Professor

Table 1.2. - The Core Team for the Alpha Prototype

Gwen Barrett - Mechanical Engineering Undergraduate Student
Shin John Choi - Mechanical Engineering Undergraduate Student
Laura Edwards - Electrical Engineering Graduate Student
Ben Linder - Mechanical Engineering Graduate Student
Andres Pieczanski - Mechanical Engineering Graduate Student
John Sieh - Mechanical Engineering Graduate Student
Brad Thomas - Becton-Dickinson Engineer
Dave Otten - Electrical Engineering Professor
Eric Vaaler - Mechanical Engineer
Woodie Flowers - Mechanical Engineering Professor

Section 1.3 - The QBC technology

The QBC method (Levine and Wardlaw, 1988) of hematology, the fundamental technology in the Walkaway, involves centrifuging a blood sample in a small tube coated with reagents. The centrifugation separates the blood into distinct bands (according to density) and each band represents different blood cell types. The blood cell types can be divided into two main categories: red blood cells and white blood cells (WBC) or Leukocytes. The WBC are further divided into two categories: Granulocytes and Non-Granulocytes. By reading the lengths of each band, and knowing the diameter of the tube, the cell counts for each type can be calculated. After centrifugation, the blood is separated into plasma, WBC and red blood cells (see Figure 1.2). The WBC region is also known as the buffy coat. The volume of WBC is small compared to that of the RBC; thus, a plastic float with the same density of the WBC is inserted in the tube prior to centrifugation, expanding the buffy coat region 10 times as it separates.

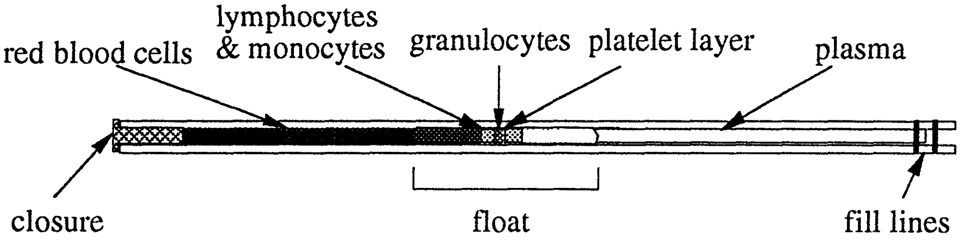


Figure 1.2. Centrifuged Blood Tube (Battles, 1993)

The different blood layers, when mixed with the reagents, contain different colors. For example, the granulocytes fluoresce yellow while the non-granulocytes fluoresce green. Two tests are currently performed in the tube: transmission and fluorescence. For fluorescence readings, a blue excitation light is focused on the tube at 90 degrees from the optical reading. The transmitted light passes through color filters before the optical sensor and allows the sensor to detect the light intensity at each small axial increment along the tube, thus determining the band widths. For the transmission reading, a white light is transmitted through the tube and with the appropriate filters, the different blood bands can be determined. The fluorescence test is done 8 times around the tube. These readings around the tube are averaged for a final hematology result.

There are many glass tubes used for blood analysis. In regards to the Walkaway requirements, there are two main types of tubes it should be able to read: Vac-Q-Tubes and capillary tubes. There are many types of capillary tubes, filled with different reagents, and these tubes are used to perform different blood tests. One such tube is shown in Figure 1.2. However, they all have the same physical dimensions: 0.09" in diameter and 3.00" long. The Vac-Q-Tube, which the Walkaway also had to be able to read, has dimensions of 0.21" in diameter and 2.74" in length.

Section 1.4 - The Walkaway

Through a thorough marketing study, the Walkaway's functional requirements were determined. Besides performing the QBC analysis, some requirements included: testing capacity for multiple tubes, reading and accommodating capillary and Vac-Q-tube tubes, and patient identification in each tube. Patient identification is a sticker with a bar code used to identify the patient. Since capillary tubes are small in diameter, it would not be feasible to attach a sticker to the tube. Thus, a plastic flag was designed to be attached to the tube without obstructing the view of the blood inside. The bar code sticker is attached to the flag. A flag was designed for both capillary tubes and Vac-Q-Tubes. Both tubes are shown with and without flags in Figure 1.3.

After a tube is filled with blood, it is put on a *carousel*. There are two types of carousel in the Walkaway. One that accommodates capillary tubes and another for Vac-Q-Tubes. Each carousel accommodates up to ten tubes. The carousel is then placed inside the *rotor*, which holds the carousel. The rotor must be in the *load / spin station* when the carousel is placed in it. This station differentiates from the *read station* which is where the tubes are read after being centrifuged. Figure 1.4 shows the carousel in the rotor and positioned in the load/spin station.

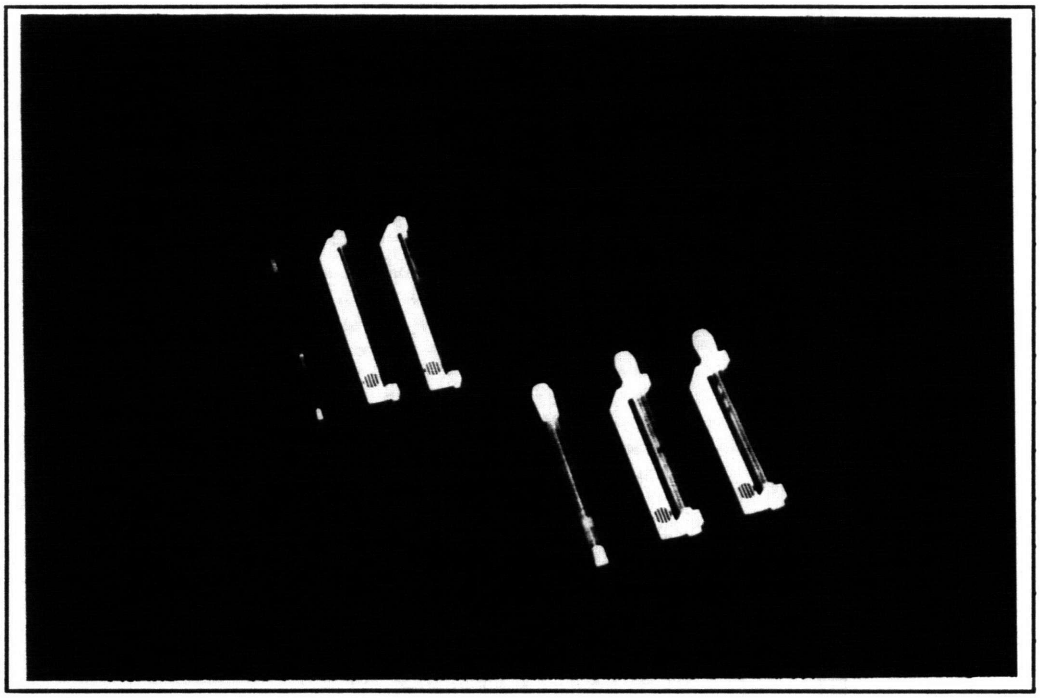


Figure 1.3. The Vac-Q-Tubes and Capillary Tubes With and Without Flags

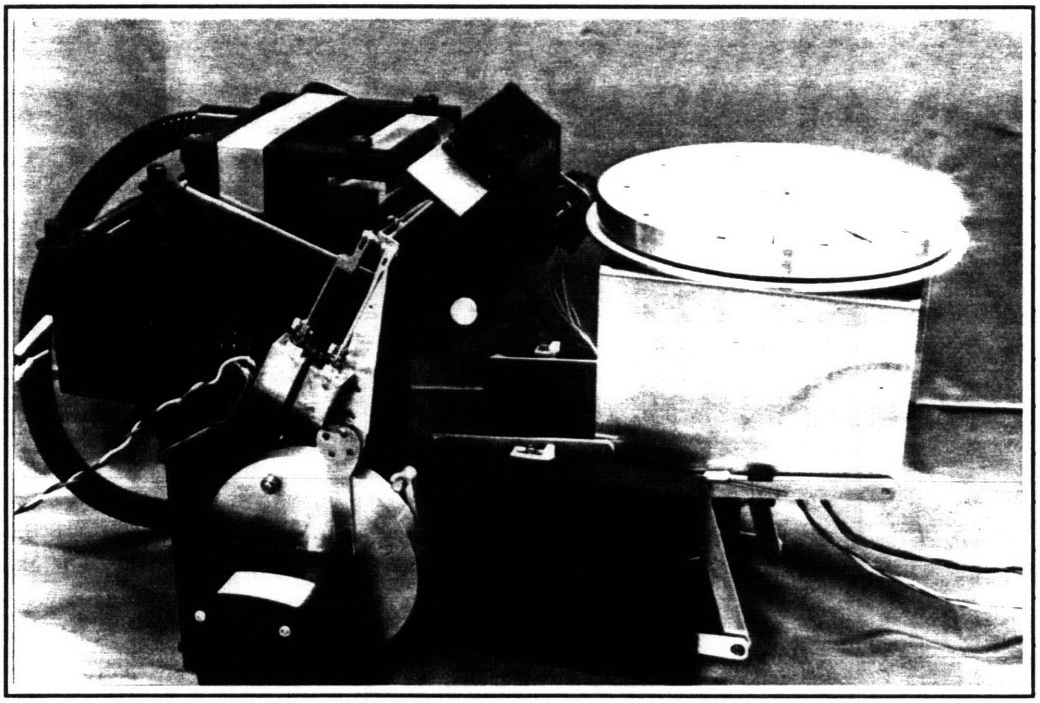


Figure 1.4. The Carousel in the Load/Spin Station

Once the carousel is in the rotor, the *lid* of the Walkaway is closed so there is no more user access to the tubes until all tests are completed. Before centrifugation, a *cover* is engaged to seal the carousel inside the rotor and hold the tubes on the carousel. After centrifugation, the cover is disengaged and the carousel with tubes are moved to the read station where the tubes are read. One tube is picked up from the carousel by the *arm*, which places it in the *indexer*. The *transport driving mechanism* which moves the carousel from the load/spin station to the read station also moves the arm. Figure 1.5 shows the carousel in the reading station and the arm being actuated by the transport driving mechanism to get a tube from the carousel.

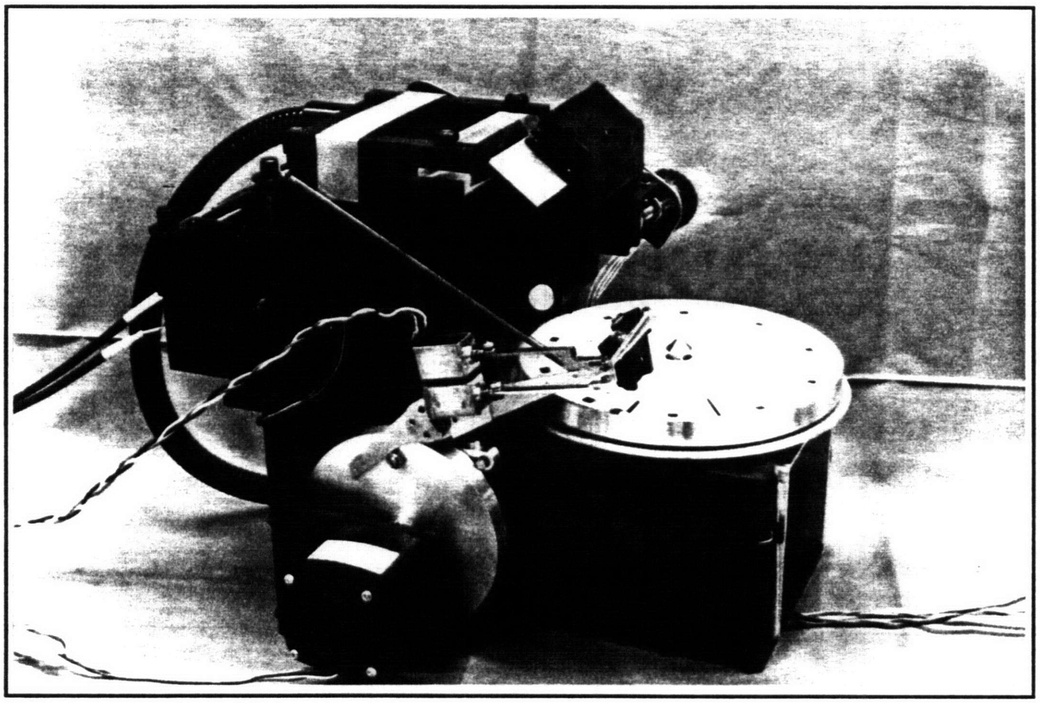


Figure 1.5. The Carousel in the Read Station and Arm Getting Tube

The indexer holds the tube while fluorescence and transmission tests are performed on that tube. As mentioned above, 8 readings are taken around the tube length and an average of the 8 readings is used for the final hematology result. The indexer rotates the tube to the 8 positions. The *optics system* reads the tubes and the bar code sticker attached to the tube via the flag. It is important that the optics system be precise when reading the different layers of blood formed in the tube. The arm puts the tube back to the carousel and another tube in the carousel is read. The *sequencer* rotates the carousel so the arm can pick-up the next tube. After all tubes in the carousel are read, the carousel is moved back to the load/spin position. Then, the lid can be opened and the tubes can be removed from the carousel.

The Walkaway alpha prototype was completed in November 23, 1993 and is shown in Figure 1.6.

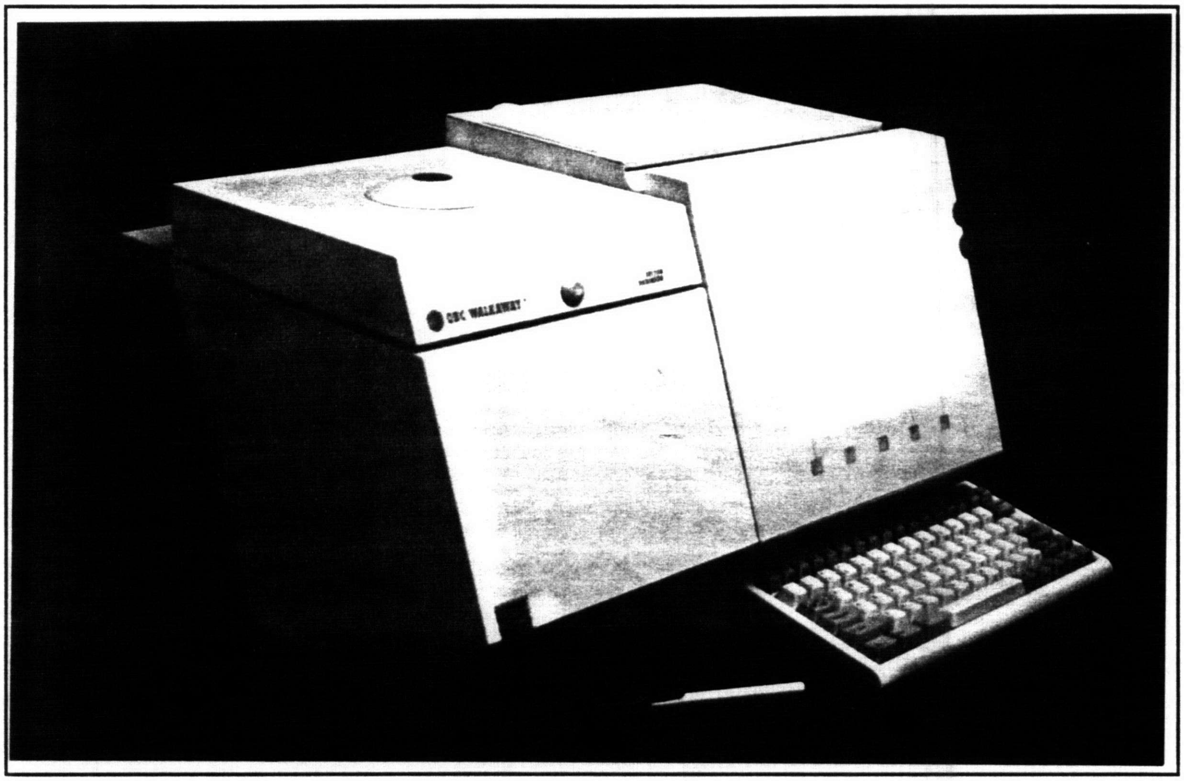


Figure 1.6. The Walkaway Alpha Prototype

The Walkaway can be divided into the following subsystems and functions:

Centrifuge subsystem comprises of the centrifuge which spins the tubes, the carousel which holds the tubes, and the cover which holds the tubes in the carousel and seals the system.

Transport subsystem moves the tubes from the load/spin station to the read station, actuates the arm, and engages the cover.
Optics subsystem: performs both fluorescence and transmission tests, including reading the tube and bar code for patient identification.
Tube handling subsystem: picks-up and returns the tubes from the carousel, and indexes the tubes in 8 positions.
Controls and Software includes all supporting equipment to run the Walkaway including all electronic equipment.
Industrial Design includes machine layout, exterior look and customer interface.
Patient Indentification includes flag and bar code.
Sequencing rotates the carousel from tube to tube for the arm to pick-up and return all tubes in the carousel.
These subsystems will be described in greater detail in the next chapter. Particular attention will be given to the Transport and Optics subsystems which was the core of my work in the Becton-Dickinson project.

Chapter 2. The Design Process of the Becton-Dickinson Project

My involvement with the Becton-Dickinson project began at the late stages of the first prototype and I will concentrate in describing and documenting my experience starting at that point. However, to fully understand what happened before this stage and the many decisions and actions taken during the conceptual phase of the project, one must read the theses written by Don Lee (Lee, 1993) and Amy Battles (Battles, 1993), which document that phase. In the subsequent chapters, I will mention some improvements in that phase although I did not participate in them. My observations are based on my experience working with the results generated during the earlier phases.

Section 2.1- The First Prototype, a Brief Summary

My main responsibility in the first prototype was to make a structure for the tube handling subsystem and some optics components. These included indexer and arm, and two fiber optic bundles used for transmission and fluorescence tests. It was necessary to obtain all requirements for the position of each component and design the structure for these components. Integrating the many subsystems was a difficult task. Being new to the project and not having the background information on the design of the total system, it was laborious to obtain and understand the necessary information for the design of the mounts for each component. Given the short time left before the presentation of the prototype, my inexperience with product design, and the urgent need to have a structure integrating the many subsystems, the structure was over-designed. Some examples include excessive number of screws and large thickness of the aluminum plates used for the structure.

The final size and shape of the first prototype was large and did not resemble a commercial product. The optic bundle, for example, had to be mounted approximately 18 inches from the table surface, an amount beyond the design specification for the Walkaway. The structure also had to be out of the path of the transport system, thus forcing the indexer and fiber optic bundle to be mounted on a cantilevered bar, away from its base. Although the first prototype did not meet many of the customer requirements specified during market study, the need of having an integrated machine was more urgent. For the first time, the subsystems which students were individually working on were integrated to form the first Walkaway prototype. This step was crucial to finalize the overall concept, functions, and layout of the blood analyzer. The presentation of the first prototype was held on May 23, 1993 at MIT. The prototype is shown in Figure 2.1.

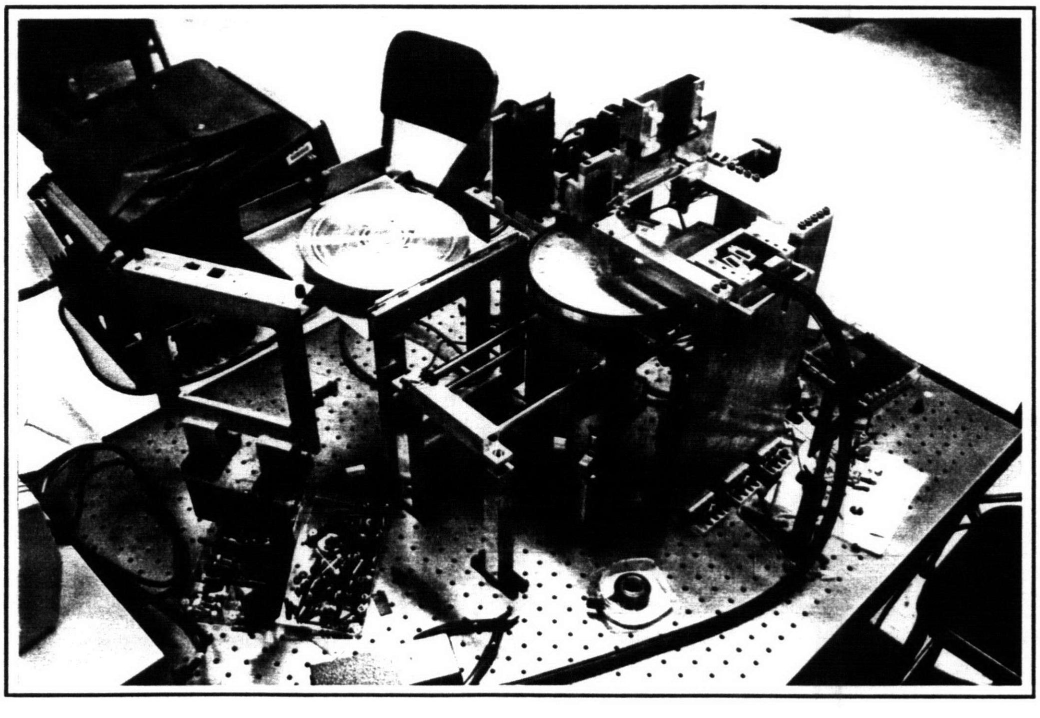


Figure 2.1. The First Prototype

The Centrifuge System

Due to the complexity of the centrifuge system and the lack of time, not all components in this subsystem were operational for the presentation. The centrifuge was not tested before or during the presentation since it did not have a blast shield to protect against a possible failure during centrifugation. Therefore, other components that were dependent on the functionality of the centrifuge were also not tested. These included the seals of the rotor, the tube behavior in the carousel, the functionality of the cover, and spinning to a speed of 11,500 rpm. Not being able to spin the centrifuge prevented the test of possible mechanical failures associated with the system, including the strength of the shaft of the centrifuge motor, strength of the transport system, vibration, and noise level. However, all components of the centrifuge system were represented in the prototype, including a mock-up blast shield. Having all components in this subsystem was important to finalize all of the centrifuge system's functions and the necessary components to achieve those functions.

The Transport System

The transport system fulfilled all its functions: to move from load/spin to read position, to engage the cover to the rotor, to actuate the arm, and to sequence the carousel. The transport was chosen under the criteria of flexibility and feasibility. These criteria were deemed most important for the first prototype. Other customer criteria generated in the House of Quality were purposefully neglected . Though the transport system was very successful in the first prototype, it would have to be modified to meet the customer requirements necessary for a final production model.

Tube Handling

The indexer was able to hold capillary tubes and index them reliably. The only functional requirement for the indexer which was not implemented in the first prototype, was being able to index Vac-Q-tubes. Given the robust performance of the indexer, its concept did not change much for the alpha prototype, even with the new function of handling Vac-Q-tubes.

The arm was also successful in reliably picking capillary tubes from the carousel. However it was not able to put them back on the carousel or dispose them in another manner. Disposal of the tubes was a function introduced late in the fabrication of the first prototype and it was dismissed for the first prototype. Thus, for the alpha prototype, given these new requirements, tube disposal and handling Vac-Q-Tubes, the arm underwent many changes in its design.

The Optics System

The optics system showed good performance. Though the resolution of the tube onto the Charged Coupled Device (CCD) was below acceptable conditions, it was clear that with better optical components the blood tube could reach the desired resolution. The CCD, the Walkaway's fundamental technology in tube reading, showed great performance. The research and tests done in the earlier phases of the project proved to very beneficial. To improve the resolution of the tube, new optical components would have to be selected including a better lens and changing the circular variable filter for a linear one. A circular variable filter was used for the first prototype since it was commercially available.

The Sequencer

The concept chosen for the sequencer was heavily influenced by the concept chosen for the transport system. To reduce the number of actuators in the prototype, the sequencer was integrated with the transport mechanism. The sequencer concept worked well and was very feasible for the first prototype. However, the need to change the transport system for the alpha prototype led the sequencer to undergo another design iteration, starting from concept generation and selection.

Section 2.2- The Alpha Prototype: the Design Process of Two Subsystems

After the completion of the first prototype, the next and last step in the Becton Dickinson project was to produce an alpha prototype of the Walkaway. The entire team and representatives from Becton-Dickinson discussed the definition of an "alpha prototype" and what should be expected from the Walkaway alpha prototype. An alpha prototype is a working model of the machine. It differs from a final production prototype in that many of its components are not manufactured using the same processes. For example, instead of having injection-molded parts, an alpha prototype contains machined parts that have the same shape as the production ones. Preferably, the material is also the same. After some discussion, it was determined that the alpha prototype for the Walkaway would not contain a PC board within its shell. Instead, the proper packaging would be allocated for this board and all other components not included inside the shell. The components and main subsystems of the prototype would be as similar to a production unit as possible.

After determining our goals for the last phase of the project, we made a plan for the final stage of the project. I was responsible for that task and used a Critical Path Method (CPM) as the planning tool. The original CPM was based on the design process for precision machine design. It is important to note that the design process for a precision machine design is different from that of a new consumer product. The CPM estimated a time for the completion of the alpha prototype that was longer than the time we had left until the end of the project. The CPM estimated about eight months time for the completion of the project; however, the last day in the MIT NPP contract, was November 3, leaving about 5 months for the completion of the project . Aware of the limited time left, we compressed and eliminated some of the activities in the CPM so it would fit into the schedule. We decided to take on the challenge of completing the alpha prototype even knowing that the time allocated was much less than ideal.

The CPM contained the major tasks necessary to build the prototype, however, it did not include any details on the process to be followed. There were no references to tools or methods for performing any of the design. The final CPM can be found in Appendix A.

The first task in the plan was to do all appropriate tests with the first prototype. Since the centrifuge was not spun due to the lack of a blast shield, we built a shield out of concrete and tested the centrifuge. We learned that despite some imbalance in the rotor, at about 12,000 rpm the imbalance had no consequences. We also learned that with the cover, the centrifuge was very noisy. The tests also allowed us to find out more about the driver board being used to control the centrifuge. The driver board used was manufactured by Becton-Dickinson and is used in their commercial centrifuges. However, because the centrifuge would undergo many design changes to fulfill the customer requirements, we decided not to perform any more tests. This was the case for all other subsystems. It was clear that the alpha prototype would be very different and spending more time studying the first prototype would not be productive.

The first step taken in the design of the alpha prototype was to assign the different subsystems to the members of the product development team (PDT). The main subsystems were separated into: optics, transport, centrifuge, arm, sequencing, electronics and software. The subsystems were assigned according to each student's knowledge and experience about that system. Two new undergraduate students joined the PDT, Gwen Barrett and Shin-John Choi, both mechanical engineers. The responsibilities of each student are shown in Table 2.1.

Table 2.1. Responsibilities of each Team Member for the Alpha Prototype

Gwen Barrrett	Industrial Design
Shin-John Choi	Latching Mechanism and Sequencer
Laura Edwards	Electronics and Software
Ben Linder	Centrifuge System
Andres Pieczanski	Tube Handling System
John Sieh	Transport and Optics System

Information on the design specifications of the Walkaway generated in the previous phases was gathered in a single document. This document was reviewed by all members of the PDT as means of familiarizing the team with the necessary specifications of their design. The final specification list can be found in Appendix B.

Section 2.2.1- The Design Process of the Transport System

The first prototype was very useful as a tool to illustrate the concept and the main functions of the Walkaway as one integrated machine. However, the details of the total system layout and its subsystems were vague. The first prototype lacked some required functions, such as supporting Vac-Q-Tubes, and returning tubes to the carousel. Moreover, the first prototype did not meet some of the design specification generated in the conceptual phase. It was clear that, though the first prototype was extremely useful and a necessary step in the design process of the Walkaway, there was a need for improvement. The main concepts for the Walkaway remained the same, but there was room for complete redesign within those boundaries. For example, the details of the concept for the transport system were the functions it had to perform. The main criterion for choosing a transport system with two linear motions in the first prototype was the flexibility it could offer. The criteria for the transport system in the alpha prototype would have to be completely different. Flexibility would not be needed in the final product, yet many other characteristics would, especially low cost. Thus, a new concept selection process had to be started for the transport system. In this concept selection process, the customer criteria would be used to select the new transport. Like most other members of the team, I started my systems from concept generation and selection.

The concept generation and selection process for the transport system began with clarifying the functions it had to perform:

- bring the carousel from the load/spin station to the read station,
- and, engage and disengage the cover.

A decision had to be made as to whether the mechanism moving the transport system should also drive the arm. This was a variable introduced in the concept selection.

Given the functions necessary for the transport system, four main concepts were studied: a rotary motion with a 90° travel, a rotary motion with 180° travel, a two axis motion (vertical and horizontal travel), and a one axis motion (only vertical travel). For every main concept, the arm had the option of being independently actuated or coupled to the transport mechanism. See Figure 2.2.

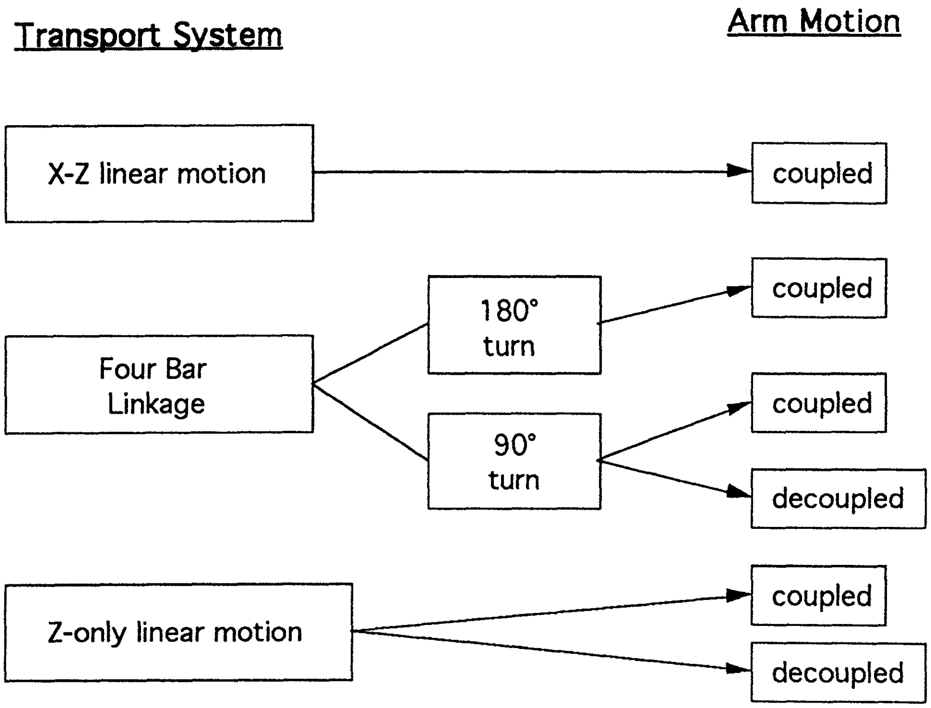


Figure 2.2. Main Concepts for Transport System

The criteria I used for selecting the transport system were determined by what I thought would be important characteristics in the transport system. The main criteria for the selection were:

- material costs
- use of standard parts
- robustness/reliability
- accuracy
- assembly
- integration
- footprint
- labor costs
- manufacturability
- vibration/noise isolation
- number of parts

I used an Analytical Hierarchy Process (AHP) as a tool to select the best transport concept given the criteria above. Before conducting the AHP (for more detail, read Saaty, 1980 and Slocum, 1992), the six concepts for the transport system were detailed. They were broken down into main components and a cost was estimated for its parts. The rotary motion was a four-bar-linkage and the linear motions were sliding tables actuated by linear screws. Because the rotary concepts were new, while the linear concept was used in the first prototype, some CAD simulation and two mockups were built to better understand the rotary concept. Even before building mockups, some foam core pieces were used to study the path of the links and their possible collision. With the information from the mockups and the simulations, it was clear that the rotary motion with 90° would generate a more compact machine. However, the 180° motion would make coupling the arm simpler. It would be similar to the coupling of the arm and transport designed in the first prototype. At the time there was little information on sequencing and whether the transport system would include actuating the sequencer. If the sequencer was to be kept similar to that of the first prototype, both of the rotary concepts would not have difficulty incorporating that type of sequencing.

The results of the AHP indicated that the rotary motion with a coupled arm was the best concept. The criteria that had the most impact on the decision was the cost. The rotary motion with a coupled arm had the least amount of actuators. The number of actuators was determined to drive the cost of the subsystem. Thus, the concepts with extra actuators were quickly eliminated, such as the two axis motion with decoupled arm and the 180° rotary motion with de coupled arm. The one axis only concept with coupled arm, while using only one actuator, was determined to be more complex, especially in integrating it with the optic system. A schematic drawing of the final transport system motion is shown in Figure 2.4. Another advantage of the 90° rotary concept was its compactness.

One of the concerns with the chosen concept was its driving mechanism. The load it would have to support due to the weight of the centrifuge system was large. One solution to the problem was to counterbalance the weight of the centrifuge.

With a transport system concept chosen, I began working on its main components. I built a transport system prototype, this time trying to represent what I envisioned as the final subsystem. I built the prototype trying to minimize its size while still maintaining the functions it needed to perform. The material used for the transport prototype was aluminum. The prototype was extremely useful. It allowed me to understand the requirements for the link connections, and the preload necessary to counterbalance the weight of the centrifuge subsystem. I noticed that torsion springs could be incorporated with the links to counterbalance the weight of the centrifuge and

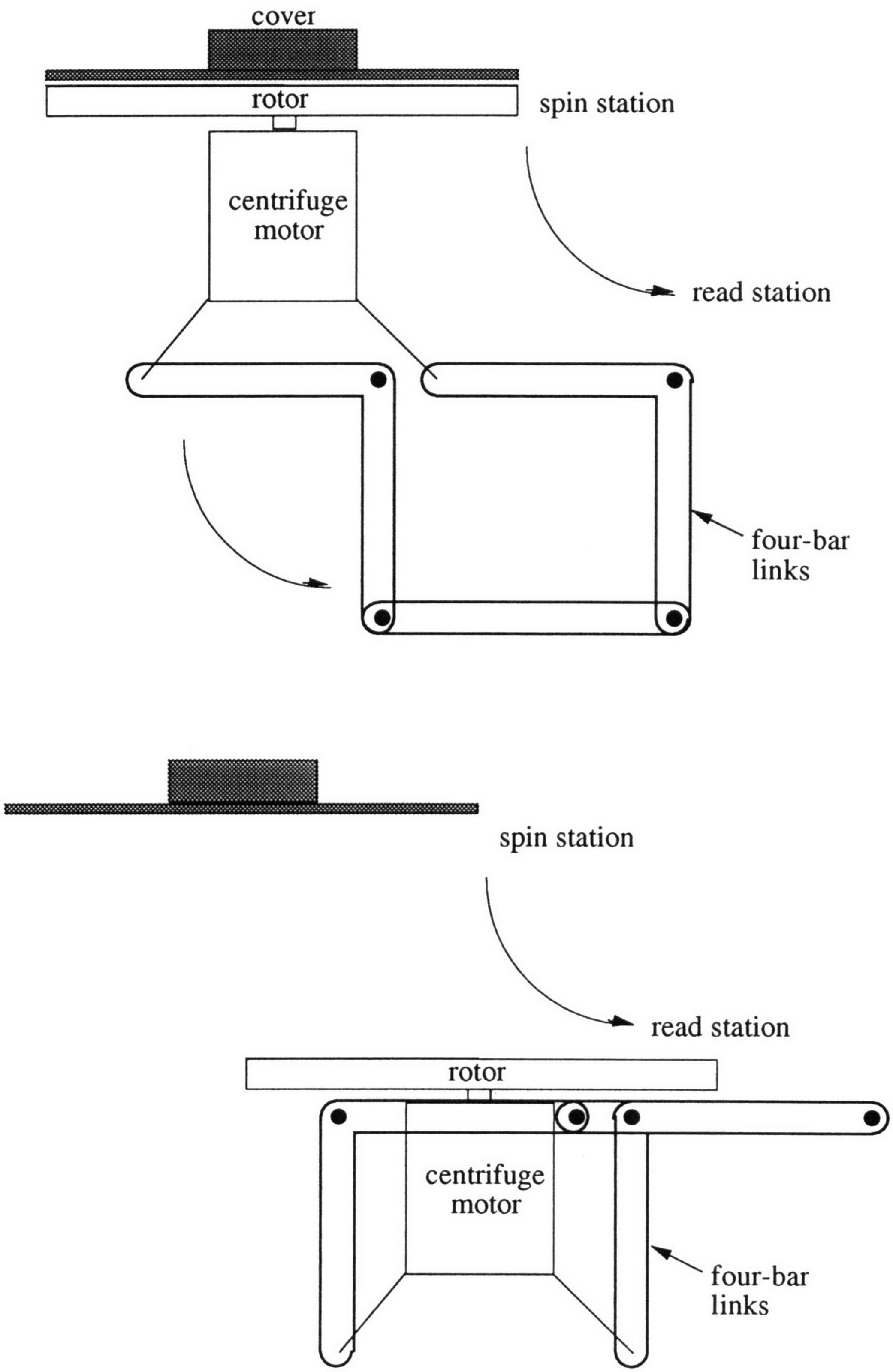


Figure 2.3. Schematic of the Transport System Motion

relieve the load of the transport driving mechanism. Using the transport prototype as a visual aid, I also determined, roughly, the final shapes of the main components of the transport system. I also determined the manufacturing processes and materials used to fabricate these components. Another benefit from the prototype was being able to show it to the other members of the PDT. They became aware of its concept, functionality, and size, which was now about 4 times smaller than the first prototype.

Only the back links in the transport system prototype had to be redesigned. The back links were connected via an aluminum plate. To prevent the transport system from warping, it was necessary that the stiffness of the two back links be equal. The original plate used to transmit torque between both links was not stiff enough. Thus, the plate was moved to a new location and its thickness was doubled. With this new configuration, the two links and the plate were determined to become one bent aluminum sheet. The links and plates fabricated for the alpha prototype are shown in Figure 2.4.

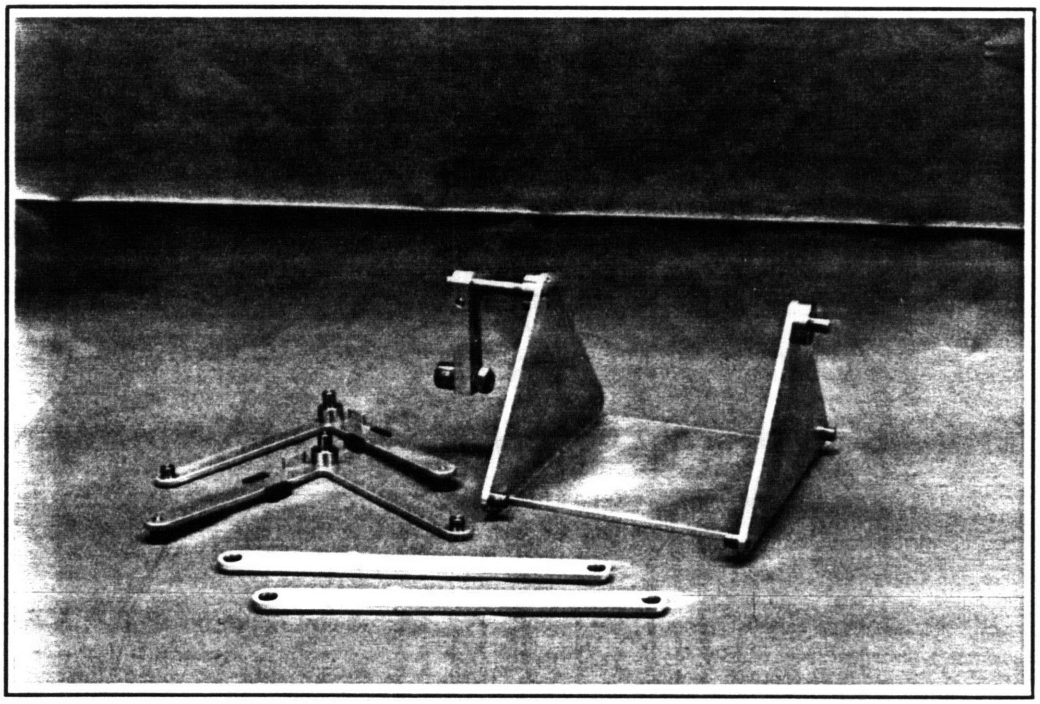


Figure 2.4. Links of the Transport System for the Alpha Prototype

The structure of the transport system was determined to be injection-molded and made out of structural foam. The decision to manufacture it this way came from the current manufacturing methods used by Becton-Dickinson for the structure of the Hemascan, a low-volume blood analyzer currently in the market. The transport structure for the alpha prototype is shown in Figure 2.5. The material used for making the alpha prototype structure was Delrin. Delrin was chosen since its properties are very similar to that of structural foam. The particular structural foam used by Becton-Dickinson for the Hemascan is GE Noryl HM3020 (high modulus grades). Table 2.2 compares the properties of these two materials.

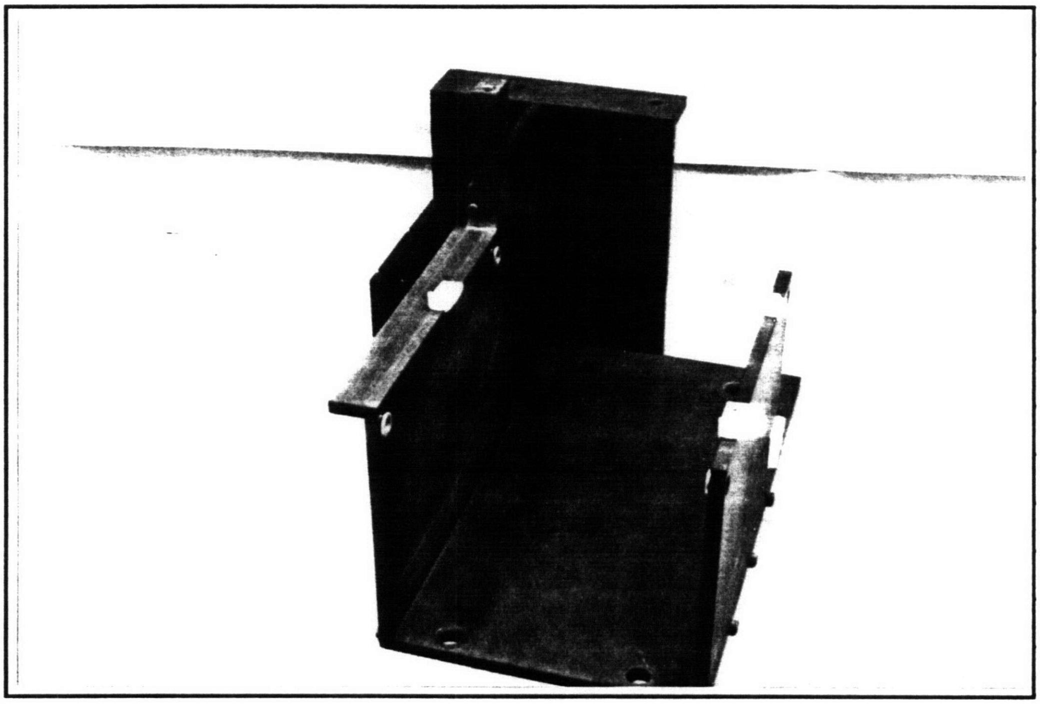


Figure 2.5. Structure of the Transport System for the Alpha Prototype

Table 2.2. Properties of GE Noryl HM3020 and Delrin

	GE Noryl HM3020	Delrin
PHYSICAL		
Specific Gravity	1.25-1.43	1.42
Water Absorption (24 hr.)	0.06-0.07	0.25
MECHANICAL		
Tensile Strength, yield (psi)	9,420-18,450	10,000
Flexural Strength, yield (psi)	16,000-22,700	14,100
Flexural Modulus (kpsi)	500-1,379	410
Hardness, Rockwell M	88-90	94
Coefficient of Friction (self)	0.04-0.42	0.3
Coefficient of Friction (steel)	0.40-0.42	0.15

The links and the mount for the centrifuge in the production stage were determined to be stamped and bent aluminum parts. Drilling the pivot points in the links would be the final operation due to the tolerances necessary for their position. The pivots between the links and the structure would be rivets. The bearing for the rivets were determined to be flanged, oil-impregnated bronze bushings, pressed into the links, structure, and mount plate. The flange would serve as spacers between two connecting links. All the decisions made when choosing the parts, manufacturing processes, and assembly sequence for the transport system were based on the reduction of cost.

The next step was determining the driving mechanism for the transport and the arm. In brainstorming different driving mechanism ideas, I had the option of placing the arm perpendicular or parallel to the plane of rotation of the transport system. I decided to keep the arm parallel to the rotation plane to reduce the frontal area of the machine. A small frontal area was one of the customers' criteria. Thus, the transport system was determined to rotate away from the front of the machine. However, due to space constraints for the user interface, the final configuration of the Walkaway was changed later. The transport would rotate from left to right.

The driving mechanism, besides having to actuate both transport and arm, also had other constraints. The driving mechanism would have to support the weight of the centrifuge system and another 10 lb force caused by a user trying to force the carousel into the rotor. The driving mechanism would also have to have enough force to engage and disengage the cover and enough force to hold the rotor fixed against aligning stops in the read station. The summary of constraints that the driving mechanism had to fulfill were as follows:

- load of at least 10 lbs at the carousel;
- enough force to engage and disengage cover;
- enough force to "bottom" the carousel onto stops;
- should not be backdrivable;
- and, should actuate arm and transport.

My initial concept was a simple link connected to a geared stepper motor that would drive the transport with 90° of its motion and use the remaining angle to drive the arm. This concept would fulfill all specifications except having enough force to "bottom" carousel. It would also require a non-backdrivable geared stepper motor with very high torque. The trade-off was between higher torque or higher speed. It was determined that the transport should take at most 5 seconds to move from load/spin to read position. Given this requirement, the highest torque stepper motor available was bought and tested. The results showed that the motor was backdrivable under the specified load.

The idea of using a cam was introduced by one of the Becton-Dickinson engineers, Brad Thomas. I investigated that concept and determined that the cam could have two profiles: one to drive the transport and one to drive the arm. The arm would be idle while the transport moves, and the transport would be idle while the arm moves. Finally, I simplified the design by having the arm preloaded in one direction and be actuated by a pin connected to the cam wheel. Thus the cam wheel would only have a profile on one side to drive the transport system and a pin on the other side to drive the arm. The pin would engage the arm when the cam follower driving the transport system reaches a constant radius and does not move. After extensive simulation using a spreadsheet trying to determine an optimum location for the cam wheel and its profile, I came to the conclusion that the cam concept could fulfill all the requirements necessary. A cam has the ability to have different gains, and I defined a profile that would have higher gains when the centrifuge is engaging/disengaging the cover and securing in the read station. These very high gains also prevents the centrifuge from being backdrivable at the load/spin position. The driving mechanism (cam) for the alpha prototype is shown in Figure 2.6 and Figure 2.7.

After the cam and follower configurations were determined, the stresses acting on the cam were calculated. The material selection for the cam was based on the stresses it would have to withstand. The main factors influencing stresses in cams are: radius of curvature for cam and follower, and materials. If the calculated maximum stress were too great, it would be necessary to change the cam design. Such changes include: increasing cam size to decrease pressure angle and increase the radius of curvature; changing to an offset or swinging follower to reduce the pressure angle; reducing the cam rotation speed to reduce inertia forces; increasing the cam rise angle; increasing the thickness of the cam, provided that deflections of the follower are small enough to maintain uniform loading across the width of the cam; and using a more suitable cam curve or modifying the cam curve at critical points, such as the loading position.

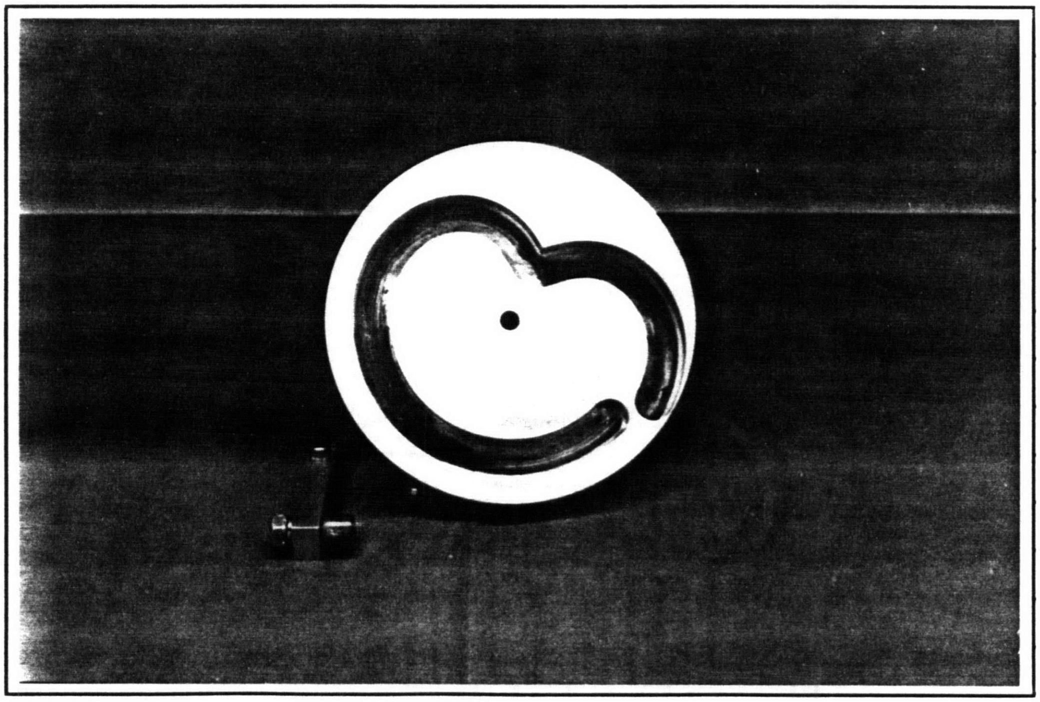


Figure 2.6. Cam and Cam Follower used as Driving Mechanism for the Transport System and Arm in the Alpha Prototype: Front Side

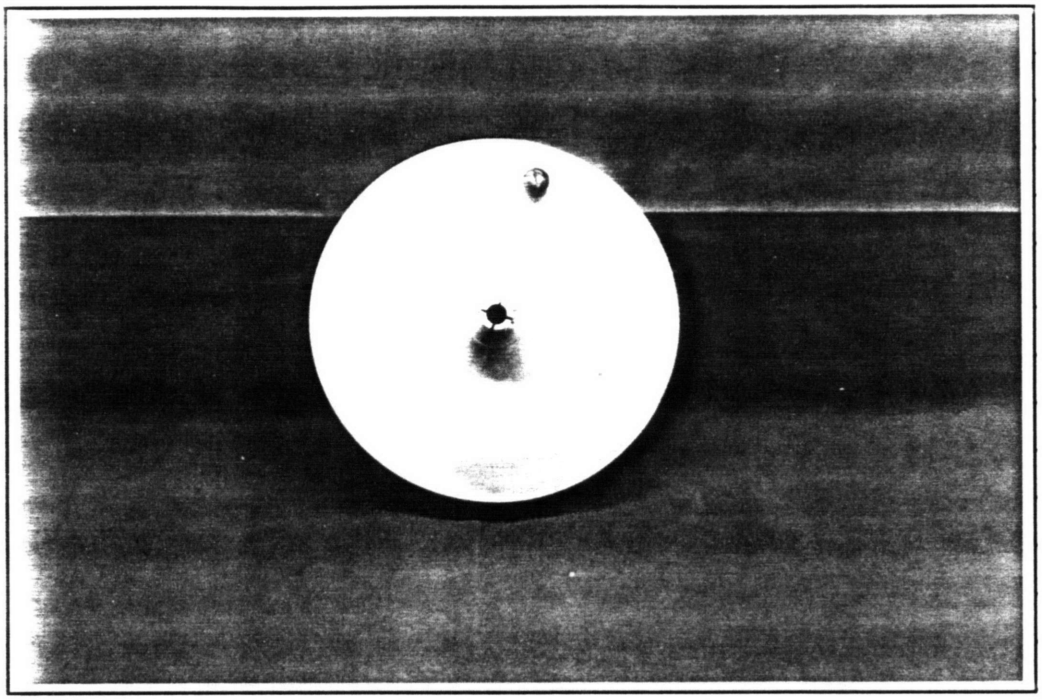


Figure 2.7. Cam Driving Mechanism of the Transport System and Arm in the Alpha Prototype: Back Side

The compressive stress, S_c (psi), developed at the surface of contact between a roller follower and the cam is given by:

$$S_c = 0.558 \sqrt{\frac{F_n(1/p_1 + 1/p_2)}{b[(1 - \mu_1^2)/E_1 + (1 - \mu_2^2)E_2]}} \qquad (1)$$

where, F_n is the normal load (lbs); b is the width of the cam (in.); p_1 and p_2 are the radii of curvature of the follower and cam (in.), respectively; μ_1 and μ_2 is Poisson's ratios for follower and cam, respectively; and E_1 and E_2 are the moduli of elasticity of follower and cam (psi), respectively. A 10 lbs. load on the carousel, when transmitted through the links to the cam, becomes a normal load of 40 lbs, due to the ratio between the links and the follower. Given the constraints of the cam size, using equation (1), the smallest possible cam follower would have a diameter of 0.50" and a width of 0.375". In the production phase, the cam could be injection-molded out of structural foam without being damaged. The cam profile would not be a manufacturing issue once the mold was made.

Coupling the cam to the motor for the alpha prototype was done using a split hub clamp. In the production phase, coupling would be achieved by molding a "D-shaped" hole in the center of the cam which would match the "D-shaped" shaft of the driving motor. This would simplify the design of the cam and reduce the number of parts.

Section 2.2.2- The Optics System

My other responsibility included the optics system. The functions that the optic system had to perform include transmission blood test, and fluorescent blood test. The main components of the optics system are shown in Figure 2.8. The function of each component is as follows:

- *the Charged Couple Device (CCD)* reads the tube,
- *the lens* focuses the tube onto the CCD,
- *the variable filter* filters the bands of light before being read by CCD,
- *the linear stepper motor* moves the variable filter to different bands,
- *the transmission light* emits a white fluorescent light for transmission test; the light rays are emitted on the same line of the CCD and the tube,
- *the fiber optic bundle* makes the light source for fluorescence test become a strip of light with even intensity,
- *the blue filter* filters the fluorescent light source and makes it blue,
- *the cylindrical lens* focuses the fluorescent light on the tube,
- and, *the halogen light source* is the source of light for the fluorescent light.

The functions of the optic system were determined during the conceptual phase of the project. It was clear that the Walkaway had to perform at least the transmission and the fluorescence tests, however, it was also determined that provision should be made to accommodate future tests which have not been defined yet. This entailed using a variable filter at the source of the fluorescent light and another variable filter between CCD and

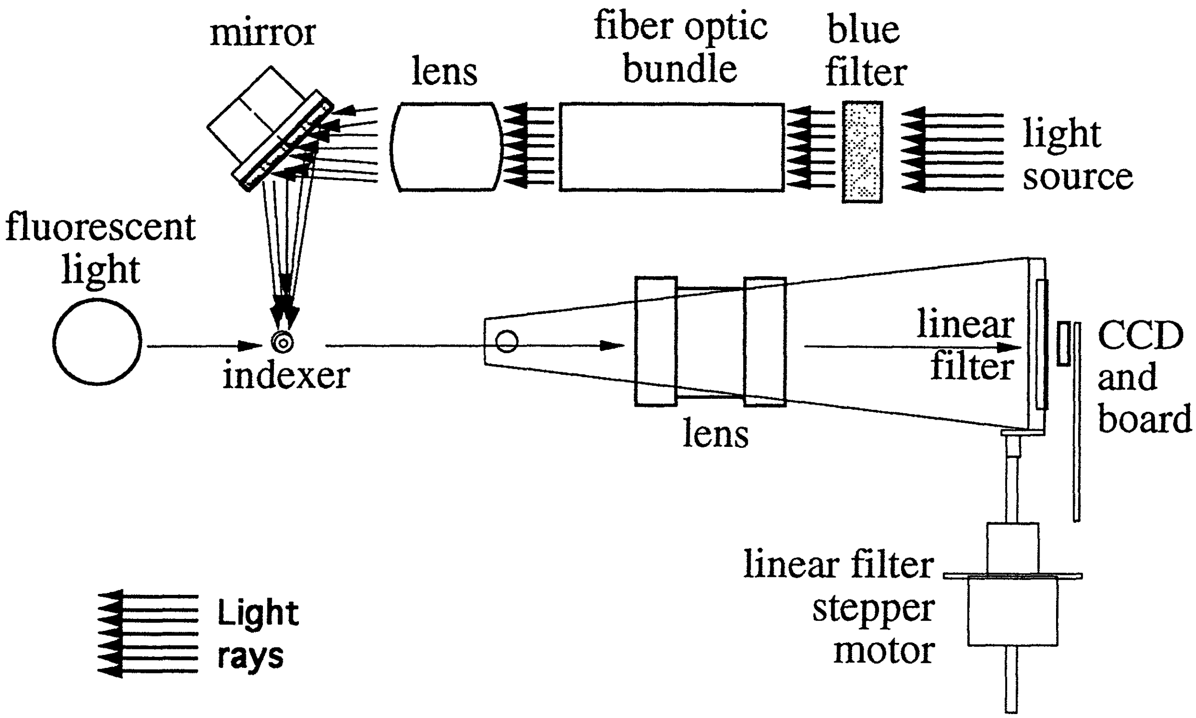


Figure 2.8. Main Components of the Optic System (side view)

tube. With this arrangement, it would be possible that Becton-Dickinson devise new blood tests for other parameters in the future and still use the Walkaway for these new test without having to modify its hardware. The alpha prototype of the Walkaway did not provide for a variable filter at the source. It was determined in the design specifications that a variable filter at the light source would not be necessary for the prototype.

Since the fluorescence and transmission tests were successful in the first prototype, one of my main tasks in the development of the optics system for the alpha prototype stage, was selecting the optical components and their layout. A new lens, with higher resolution, was selected. The transmission light was changed from a fiber optic bundle and light source to a simple fluorescent light bulb and an inverter, thus reducing the cost from $500 to $16.

For a shorter layout of the Walkaway, the transmission fiber optic bundle was set horizontally, and a mirror was used to reflect the transmission light onto the tube.

Alignment requirements of the Optical System

The alignment requirements of the optical components are as follows:

- the CCD must align with the tube;
- the lens must focus the 3 inch tube on the 2 inch CCD;
- the transmission light must be aligned with the tube;
- and, the fluorescent light must be focused on the front half of the tube and must be aligned with the tube.

These alignment requirements generated a large number of adjustments in the mounting of each component to the structure. To require the components to be aligned through tight manufacturing tolerances would increase the manufacturing costs substantially. In some cases, the supplied components already contained manufacturing imprecision that were greater than the allowable optical alignment amount. This included the CCD, whose parallelness and height varied from piece to piece and the lens whose focal length also had too much variation. Given that the axis of the indexer was fixed, i.e., the axis of the tube, the following adjustments became necessary:

- a rotation and translation of the CCD (to adjust the parallelness and height);
- a translation for the lens (to adjust focus between CCD and tube);
- two rotations for the mirror (to adjust parallelness and position of the light with respect to the tube);
- translation of the cylindrical lens (to adjust focus of the fluorescent light on the tube);
- rotation and translation of the transmission light source (to adjust parallelness and height with respect to the tube).

For assembly purpose, I decided to incorporate as many optic components possible in one structure. This would allow the optics to be pre-aligned as a sub-system. Once aligned, the optics system could be integrated with the other subsystems. It also made sense to incorporate the tube handling system with the optics since the optic components and the arm mechanism have to be aligned with respect to the position of the tube. Finally, the sequencing sensors were also mounted on the optics structure since it was conveniently located.

Much thought was put in the design of the adjustment and clamping mechanisms for the optics components. They were design for easy assembly and adjustment. A clip-on clamp holds the lens and the fiber optic bundle. Both in the production model and alpha prototype, these clamps were determined to be stamped and bent sheet metal. The adjustments for the mirror and CCD were designed to be achieved by turning two screws. The CCD had two vertical screws holding the two upper corners of the CCD board. The CCD board was placed on a spring which pre-loaded it onto the screws. By turning one screw or the other, the board would change its angle, and by turning both screws in one direction, the CCD board would travel up or down. Thus, two degrees of freedom (vertical travel and one rotation) was achieved with two screw adjustments.

As with the transport system, the structure for the optics system was determined to be injection molded structural foam. Thus, I designed a structure that would contain all the optical components (except the transmission light) and the tube handling mechanisms, arm and indexer. The optics structure is shown in Figure 2.9. The transmission light was left out of the optics structure since it was in the path of the arm and tube motion. Figure 2.10 shows the optics structure with all its components mounted, including arm, indexer, and sequencing sensors. Careful attention was spent to make the structure "injection-moldable", but due to the many components it had to support and the constraints that each component imposed on the structure, the version made for the alpha prototype cannot be injection-molded without many actuations in the mold. In order to make the optics structure easier to injection-mold, the arm will need some redesign to accommodate the changes in the structure.

Section 2.2.3- Integration of the Alpha Prototype

At about two months before the scheduled completion of the alpha prototype, we started discussing the configuration of the machine and its supporting components, such as keyboard, disk drive, and screen. At that late stage, the configurations of the subsystems were already determined, leaving very little room for many possible layouts of the machine. We decided to have the centrifuge on the left side and the optics on the right side, to allow enough frontal area for the screen.

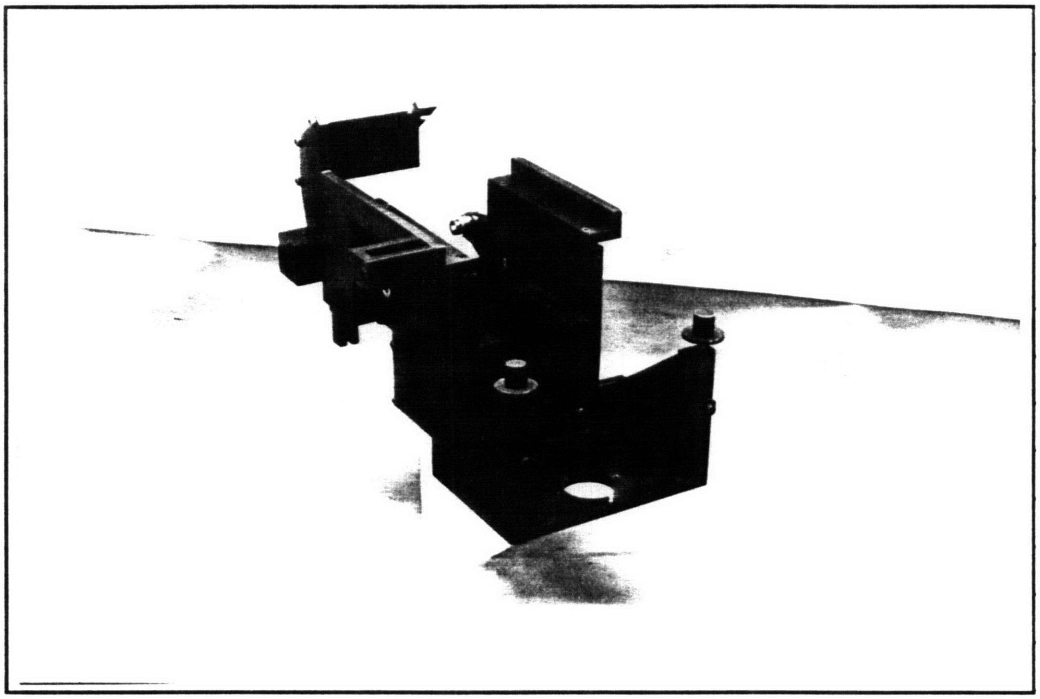


Figure 2.9. Structure of the Optics System for the Alpha Prototype

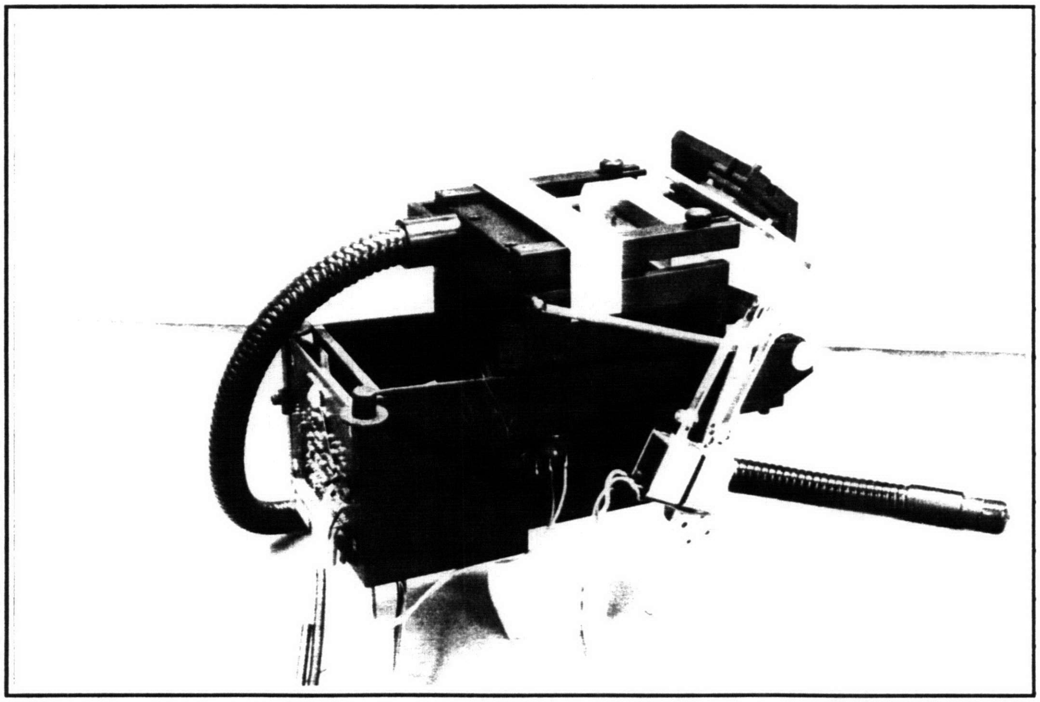


Figure 2.10. Structure of the Optics System for the Alpha Prototype with Optical Components

As we drew closer to the presentation date for the alpha prototype it was clear that the machine would not be ready by November 3rd and the presentation was delayed to November 23rd. When integrating the different subsystems, many problems arose. Some subsystems were late to be completed or needed reworked. This forced the testing of the machine to be rather late and time ran out before all the problems could be fixed. Some of these include:

- the centrifuge noise and vibration level were high,
- the linear variable filter had a very low transmission,
- the arm could not pick-up tubes in certain locations of the carousel,
- the transmission light did not have proper alignment,
- and, the centrifuge motor had large cogging forces and would not allow for sequencing.

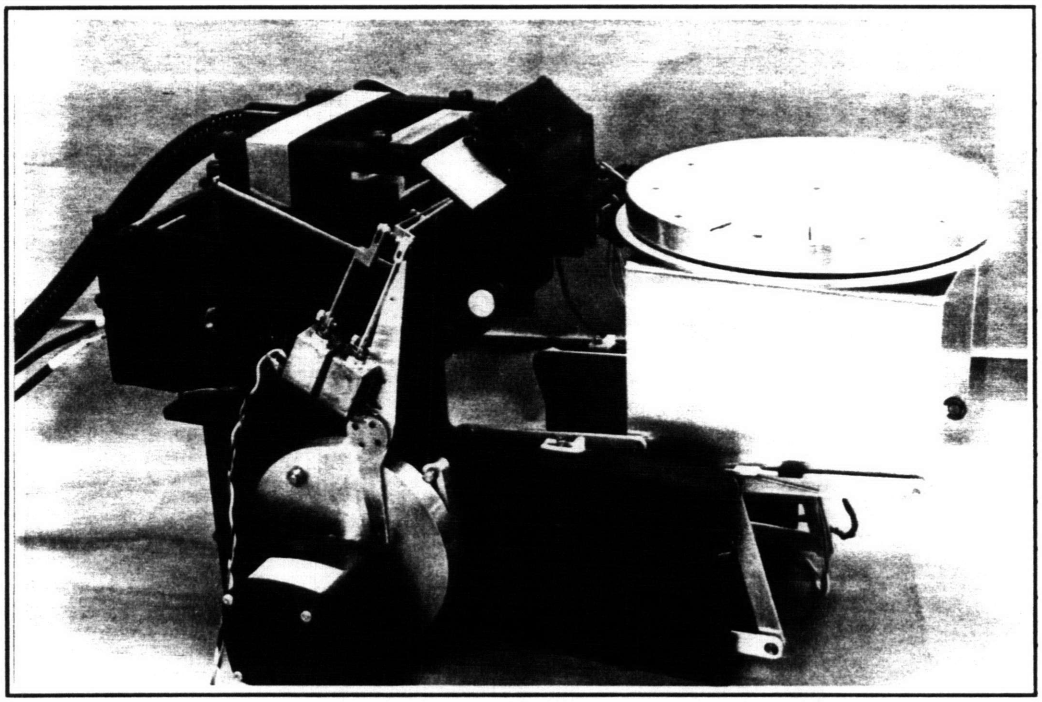


Figure 2.11. The Alpha Prototype Centrifuge, Transport, Tube Handling, and Optics Subsystems Integrated

Chapter 3. A Critical Review of the Becton-Dickinson Project

In this chapter, the Becton-Dickinson project is critically analyzed. The reader must note that despite the many problems described in this chapter, the success of the Becton-Dickinson project is unquestionable. Since the completion of the project, the Walkaway alpha prototype has been shown to various Becton-Dickinson representatives in Europe and United States and has gained much approval. Rudy Rodriguez, Vice President of Research and Development of Becton-Dickinson Primary Care Diagnostics division, wrote: "I believe this program was a good investment for Becton-Dickinson and a net win-win for both organizations. Would I do it again? Yes, absolutely."

For equal success, future NPP projects could imitate the design process followed in the Becton-Dickinson project. The most successful activities are emphasized in this chapter to solidify the winning actions in the current NPP design process. However, not all projects are completely perfect, and the Becton-Dickinson project has also had its obstacles. These obstacles are also described below. For even greater success, future NPP projects should avoid committing the same mistakes. A description of an improved project organization and design process are given in Chapters 4 and 5.

Section 3.1- Project Organization

Project management

The intention of the NPP is not to have one aggressive leader in control of the entire project. It focuses on having every member of the product development team (PDT) taking some responsibility in leading the project. The management and leadership experience gained by the students in the project is invaluable. However, it is important to have one person in charge of overseeing the entire project, a person responsible for facilitating and administering it. That person is the project leader.

The leadership in the Becton-Dickinson project suffered an unavoidable change in the middle of its development. This change violated one of the points for effective leadership: "the leader has responsibility that endures over the entire duration of the development program" (Clausing, 1993). Although having the leader remain in the project throughout its duration is a crucial need, it is practically impossible to enforce it. It is very important that future project leaders in the NPP be professors who have a low probability of leaving the job. If a project leader decides to leave the project, provision should be taken that a new leader be assigned to the project while the old leader is still present. This overlap will allow the new leader to update himself/herself to the project while the old leader is still in charge. Thus, when the original leader leaves, the new leader can take an active role immediately.

Due to the limited resources in the NPP, the time a leader allocates to the project is very limited. In the Becton-Dickinson project, the little time spent on the project by both its leaders, led them to lack some of the important points for effective product leaders. These include:

- taking an active role in managing conflict and preventing problems with the team performance, exemplified by the initial conflicts between team members, and the lack of productivity of some members;
- taking an active role in preventing delays in schedule, exemplified by the delay in the final presentation and the lack of time to optimize the alpha prototype;
- and, taking an active role in creating a good strategy and a thorough product development plan, exemplified by the many different approaches taken by the team members in designing and integrating their subsystems.

Group Dynamics and Team Selection

The NPP leader should ensure that the PDT is multifunctional and endures the duration of the development program. Again, the lack of resources in a NPP project limits the number of student or technical consultants in the fields involved with the project. The NPP leader must make the best use of its resources by hiring students that have multifunctional background, such as a student with industrial design and machine design experience, or manufacturing engineering and product design. This will allow the NPP to have a multifunctional team even with its limited funding. In the Becton-Dickinson project, the lack of a manufacturing engineer is clear in the detail of the parts in the alpha prototype. Almost no part was designed to adapt to the manufacturing capabilities of Becton-Dickinson, nor was there any specification as to what suppliers or standard parts to use. This will prove to be a problem when the product goes into production. It is likely that another iteration in the design will be necessary to adapt many of the parts to current manufacturing and assembly capabilities, thus extending the total cycle time for the Walkaway. It is important that a member of the team becomes responsible for ensuring that manufacturing specifications be met.

Since not all NPP projects have the duration of 2 years or a start at the beginning of a school year, keeping students in the project throughout its duration is impossible. Thus, it is necessary that, like with the project leaders, new students enter the project before a team member leaves. In the Becton-Dickinson project, only one of the original members and one technical professor lasted throughout the product development process. All other positions were modified in the middle of the project and some positions were eliminated. This change in group composition caused a number of negative effects, including:

- lost of useful information and knowledge about the customer,
- lack of continuity,
- and, reduced teamwork.

The most critical consequence was the loss of valuable information gathered in the initial phases of the project. Loosing a team member who took part in the market study from the beginning is losing investment done in that phase. The participation of all members of the PDT in a meticulous conceptual phase, with in-depth market study, is done so engineers understand the customer needs. Much information obtained during this phase cannot be documented. The engineers that entered in the middle of the Becton-Dickinson project were forced to work with only documented information. An overlap between the incoming student and the outgoing one would allow better information transfer.

Trust

In the Becton-Dickinson project, the members of the PDT had to rely heavily on trust; trust that the other members were committed to the project, trust that their design process would generate a successful subsystem, and trust that the documented design specifications would generate a successful product. Having to rely on trust should be avoided through: first, good team building by making sure members last the duration of the development and there is no lost information; second, good design process where the total concept chosen is a successful one and the subsystems are divided with thorough detail so every member of the PDT is fully aware of what each subsystem will be like, how it will perform, and how it integrates with the other subsystems; and third, through regular reviews of each member's work to update and obtain consensus from the PDT.

Communication

E-mail communication between the members of the PDT, including the participation of engineers from Becton-Dickinson, was extremely successful in this project. E-mail was easily accessible to all members and the communication within the team was great. However, there were a few occasions when the communication between the PDT and Becton-Dickinson was less than ideal. Such occasions should be avoided in future projects. One example was the dual rotor concept generated during the conceptual phase of the project. The dual rotor concept was discontinued even after determining that it was the best concept and spending much time on it. The lack of communication between the PDT and Becton-Dickinson allowed Becton-Dickinson to lose track of the magnitude and cost of the product. Many weeks later, when they realized the problem, they immediately changed the concept. The situation, as described by one of the team members (Battles, 1992), was a "crisis":

> " The project had been essentially turned upside down at this point. Not only were drawings called back from the machine shop, but also, purely by coincidence, new advisors and students were joining the project to replace others who had left due to graduation and new

job opportunities. In a one week period, the project took on a whole new feel. Spirits of students and advisors on the project were mixed. No one was excited about the notion of backtracking and disposing of months of work. On the other hand there was a renewed enthusiasm for the project and a sigh of relief in appreciation of the simpler design task ahead."

Constant communication is essential in the project. The work lost could have been avoided with better communication.

Section 3.2- The Design Process

Strategy

"It is my absolute conviction that you can outmanage your competition by having brilliant strategies but those brilliant strategies have to be executed brilliantly."

-Lou Gerstner
RJR Nabisco, CEO

It is quite clear that having a good strategy is not good enough anymore. Many companies are already aware of the most recent design processes, including Concurrent Engineering, Total Quality Development (TQD), Total Design, Taguchi, and Design for Manufacturing and Assembly (DFMA). The competition is also aware of all the latest design tools available. What separates a good product development team from its competition is the manner in which the process is executed. Having a good strategy is just not enough. (Irvin and Michaels, 1989) The design process used in the Becton-Dickinson project was basic concurrent engineering. The tool used to map this plan was the Critical Path Method (CPM).

The CPM was a very useful tool in the Becton-Dickinson project. For most part, it allowed all team members to review their current status and see whether they were late or not. The CPM was also useful in checking the progress of each team member during the weekly team meetings.

A CPM was used to organize the final stage of the project, the alpha prototype phase. The original time estimated to perform all necessary steps to complete the alpha prototype was of seven and a half months. But since the project was originally scheduled to end in November, there was only five months left for that phase. It was clear that the alpha prototype would be late and its development would be very rushed, even before the alpha prototype phase began. A means to avoid getting in such situations is better planning. Future projects should roughly map the entire project and allocate approximate time duration for each main phase. For example, a NPP project with a 2 year span could be mapped out to have a market study phase of about 8 months, concept generation and selection of about 4 months, design and development of a first prototype in about 4 months and a alpha prototype phase of about 8 months. Presentations and reviews with the sponsoring company could be scheduled at the end of each main phase. This rough planning of the entire project would avoid situations similar to the Becton-Dickinson project, where only 5 months were left to develop the alpha prototype.

Market Research

The market research performed by the Becton-Dickinson team was well executed. Through personal interviews, the team members were able to learn very quickly about the many issues involved in the development of a blood analyzer. Detailed knowledge about the customer and their needs was obtained effectively. Future NPP should attempt to imitate the market research done in the Becton-Dickinson project. The market study details for this project can be found in Richard Wong's Masters thesis (Wong, 1992). Image KJ and Kano questionnaires could also be incorporated to the market study performed in the NPP projects. This could give further insight of the customer needs and rank them in order of importance. These methods are better described in Chapter 5. Also, it has been shown that information gathered through focus groups are usually 30% incorrect (Zangwill, 1993). Perhaps focus groups should not be used in future NPP projects.

House of Quality

The role of the House of Quality in the Becton-Dickinson project was one of the subjects of Amy Battles' Masters thesis (Battles, 1993). She concludes that the House of Quality was not an appropriate tool for use in the Becton-Dickinson project. The negative impressions of the House of Quality include the extremely time-consuming task of completing the tool and the unproductive results it generated. In the Becton-Dickinson project, target values for the engineering characteristics were not set. This failure was attributed to the PDT's lack of knowledge and expertise in the hematology field.

I believe the House of Quality was a beneficial tool in this project and could have been even more advantageous if properly used. The House of Quality has many other benefits other than "setting target values and helping marketing communicate with engineering". The engineering requirements generated are used as criteria for selecting the product concept. This is one of the ways the voice of the customer is used to develop a new product. Benchmarking is another valuable benefit from the House of Quality. Benchmarking values are used to set the target values for engineering characteristics. The PDT could have also requested information from Becton-Dickinson, experts in the hematology field, to help set these values. Finally, the House of Quality helps deploy the engineering characteristics to the subsystems and piece-parts of the product. Quality Function Deployment (QFD) structures the entire design process and the House of Quality should be used not only in the conceptual phase, but also in the design and production phases.

Selecting only the most important voice of the customer is an important step in the QFD process. The "intermediate" size House of Quality should be no bigger than 30 x 30 (Clausing, 1993; Zangwill, 1993). This makes the process much quicker and will focus the attention of the group on the most important issues. To select the voices, the PDT could use the multi-pickup method (MPM) described in Chapter 5. A small House of Quality will not lead to very general engineering constraints. A smaller number of "voices" does not mean more general statement that encompass many voices; it means only the most important voices are used to focus the product development.

The large House of Quality generated by the PDT consumed valuable time and effort, bringing the whole team down and leaving a negative impression of the tool. Most important, valuable information in the House of Quality, such as the engineering constraints and their target values, were left incomplete. The most important conclusion drawn from the Becton-Dickinson project concerning QFD is that the PDT must fully understand the design process, how to use the tools, and the purpose of the many steps. QFD will produce great results if the PDT knows how to guide it towards their own benefit.

Technology and Total System Concept Selection

The Pugh concept selection was very successful in the Becton-Dickinson project. Pugh charts give the PDT the liberty to work on the negatives and enhance the positives of each concept, generating new concepts or ideas in the process. The ability to quickly identify a concept's weakness is one of the benefits of the Pugh chart. A more numerical or weighted concept selection tool, such as the Analytical Hierarchy Process (AHP) might not allow the flexibility of generating new concepts based on the weakness and strength of the original concepts.

The PDT conducted the Pugh selection process very well, remembering the need for iteration and the use of engineering characteristics from the House of Quality as the criteria for selection. One suggestion for future concept selection sessions is that once the large number of original ideas has been narrowed down to only a few, a greater level of detail could be used in the description of the concepts left. It is important to be thorough in the description of these concepts so the PDT can vote more accurately in all criteria. The vague description of the dual rotor concept lead the PDT to misjudge the cost and manufacturability of the final product.

Once a final concept is chosen, it is extremely critical to define that total system concept *in detail*, including all the subsystem technologies, subsystem specifications and interface, machine layout, and aesthetics. In this manner, all members of the PDT are aware of what the other members are working on and how all the subsystems interface. In the Becton-Dickinson project, given the rush to meet the presentation date, each member of the PDT took a subsystem as their responsibility and began detailed design hoping that integrating it all together later would not be a problem. Little attention was given to the product design specifications (PDS) . This resulted in a prototype that needed much rework and most subsystems suffered major conceptual changes for the alpha prototype. Investing time at the end of the concept selection to detail the subsystems of the entire product can save time when integrating the entire machine. Also, investing some time generating and selecting concepts for the subsystems can avoid future design iteration of subsystems and shorten the cycle time of the product development.

Progressive Freeze

Freezing the decisions made is an important step in the design process. It avoid iteration and lost time. At the end of concept selection and with clear description of the total system layout, the PDT should have had a progressive freeze with the participation of all the managers involved from Becton-Dickinson. This step would have sealed the product concept and symbolize complete agreement between the parties involved. This freeze, however, can only be performed once the information on the winning concept of the Pugh selection process is detailed. The insufficiency of detail in the presentation of the dual rotor concept allowed the Becton-Dickinson management to accept the concept at first and give it the go ahead. As the details of the concept became explicit, the dual rotor was found too complex and expensive and a new concept had to be selected. At the end each important stage in the design process, the NPP PDT could perform a ceremony to reach agreement. An example of such ceremony is given in Chapter 5.

Sub-system design

It is important to have proper deployment from the conceptual phase to the design phase. QFD is a good tool to insure that the voice of the customer is transmitted to the design of the total system and also the subsystems. In the Becton-Dickinson project, once the winning concept was selected, we were very eager to divide the Walkaway in subsystems and begin its design. After spending so much time in the conceptual phase and given the short time left for the production of the alpha prototype, it was difficult to restrain ourselves from doing design of our own subsystems. However, this prevented the optimization of the Walkaway as a whole. A total product design and optimization is more beneficial than subsystem optimizations since it improves the integration of subsystems and it produces a better machine layout. Subsystems, however, also do have to be optimized. The Becton-Dickinson PDT did a very good job optimizing the subsystems, but could have also spent more time during the early stages of the alpha phase, discussing the overall layout and integration of the machine. Time spent in the early stage of the alpha phase could have saved some time when integrating the subsystems. The presence of an industrial designer earlier in the alpha phase could have helped solve this issue, however, the limited resources available for NPP projects must also be considered.

It is necessary to have a well specified design process for the PDT to follow. The entire PDT should take part in the concept selection process and total system configuration. Tools such as the Pugh chart, give facts and the team does not have to trust that each individual designer has the ability to produce the same results using their own methods. Even after the subsystem concepts have been well defined and a good plan has been detailed, the PDT should be constantly reviewing each other's work and evaluate each member's performance and results. This will allow total team participation in the work done by individual members.

It is essential to have complete information on the technologies and the engineering specifications before entering the design phase. All customer requirements should be determined and frozen with the completion of the product design specifications (PDS), otherwise this can cause delays in the development process. One example in the Becton-Dickinson project was the automatic disposal of tubes. The requirement for an automatic disposal of tubes was introduced by Becton-Dickinson only after the selection of the Walkaway concept. This key piece of information could have changed the outcome of the concept selection process. Moreover, its late introduction forced the PDT to spend time trying to accommodate this new requirement into the final concept, yet it did not allow enough time for its realization. The outcome was lost time and effort, but no auto disposal for the first prototype. Future NPP projects should beware of the introduction of new requirements in the middle of the design phase. It can disrupt the focus of the PDT efforts and the design of the new product.

Introduction of New Technologies

Similar to new customer requirements, new technologies introduced late in the development process can also cause delays. Three such examples in the Becton-Dickinson project were the linear variable filter, the lens, and the light pipe. On the other hand, mature technologies, researched and tested during the conceptual phase, exemplified by the CCD, can reap success in a product. It is crucial that the technologies to be introduced be developed before entering the design phase. During the design phase, no time should be spent by the PDT, researching and experimenting with new technologies.

After the completion of the first prototype, it was suggested to replace the circular variable filter for a linear variable filter in order to improve the quality of the tube image. The circular variable filter was used in the first prototype due to its commercial availability. The linear variable filter concept was sent to a major filter manufacturer who promised that the filter would meet the specifications desired. The delivery date of the filter was scheduled to be about one month before the presentation of the alpha prototype. Provisions were made in the design of the machine to accommodate the filter when it arrived. Due to problems with the manufacturing of the filter, the final delivery date of the filter was only within one week of the presentation of the alpha prototype. Moreover, the filter was far below the required specifications and could not be used. Therefore, the alpha prototype had no linear variable filter and was not able to do the necessary blood tests during the presentation.

After the completion of the first prototype, the lens used was determined to be unsuitable for doing the blood tests since it lacked the necessary resolution. Thus, even during the design phase of the project, a new lens had to be selected and tested. Fortunately, a better lens was available commercially and the resolution of the tube image was improved. Also during the design phase, a new concept for light transmission was introduced to replace the fiber optic bundle. This new concept was a light pipe. Time and effort was spent in the design phase to research the feasibility of that concept. If the light pipe were determined to be feasible, it is possible that the time needed to develop it adequately would have surpassed the time available and the outcome might have been similar to that of the linear variable filter. Instead, the light pipe was proven not to be a suitable for replacement for the fiber optic bundle. The linear filter, lens, and light pipe should have been researched during the concept selection process. None of the designs should have been started without all the necessary data.

To contrast these negative examples, a new technology, introduced in the Walkaway that underwent a thorough maturing process was the Charged Coupled Device (CCD). It was introduced as a concept with skepticism, but due to the lack of information on it, thorough research and experimentation was done on the CCD and other reading devices to obtain all the appropriate data. With new and complete information, the CCD concept was chosen unanimously. The team was confident that it was the best choice and a winner. In their minds, the PDT had frozen the CCD concept and agreed it would not change. It is exactly this confidence and thoroughness that the PDT must have toward the entire machine and all its technologies. Despite the problems with the first prototype, the CCD was a very robust component. It performed its function with the desired specifications and was the only component in the first prototype that remained unchanged in the alpha prototype.

It is imperative that all concepts be fully mature and all engineering specifications determined by the end of the concept phase. The PDT must freeze the specifications and technologies at that time, so that valuable time and effort are not spent doing research during the design phase.

Benchmarking

Given the short time for the development of the alpha prototype, the Becton-Dickinson project had to omit performing competitive benchmarking. Without benchmarking, the design engineers do not have a good reference of how well the subsystem has to perform. In many cases, the designer spends time designing subsystems that have been optimized by other companies. As one engineer from Cadillac once told me: "You don't have to re-invent the wheel. Just improve the heck out of it."

A subsystem that could have been easily benchmarked was the centrifuge. Becton Dickinson has designed and manufactured centrifuges for many years and instead of copying their centrifuges, a new one was made. In both prototypes, the system's noise and vibration levels were unacceptable. In retrospect, we could have used Becton-Dickinson's expertise better to help design and build the Walkaway's centrifuges.

Parameter design, Taguchi optimization

The alpha phase of the Becton-Dickinson project also had no time to perform optimization experiments, also known as Taguchi or parameter design. The consequence of little optimization is lack of robustness in the subsystems. One example of lack of robustness within a subsystem is the vibration mounts for the centrifuge. One example of lack of robustness in the integration of the machine was in the interface of the receptor cup (part of the indexer) and the carousel. The first example could have been improved with benchmarking and parameter design. The latter example could have been avoided by first designing the total system as a whole as opposed to dividing it in subsystems.

The design of the centrifuge system for the alpha prototype contained four vibration mounts at the upper edge of the motor. However, the centrifuge was extremely noisy and not well isolated from the rest of the machine. As an experiment, the original design with four rubber mounts was reduced to three softer mounts, as in the Becton-Dickinson centrifuges. The isolation of the centrifuge was improved considerably, as was the noise of the centrifuge without the cover. This is an example where having time to perform Taguchi experiments would have helped. By doing a failure analysis of the centrifuge system, at the top of the fault tree would be "centrifuge does not spin". One of the causes of such occurrence would be "centrifuge is too noisy". This in turn would lead to the control factors: position of the vibration mounts, number of vibration mounts, and flexibility of the vibration mounts. A series of experiments could have determined the best values for these parameters and most likely, the result would have been improved. Future NPP should allocate enough time to perform Taguchi experiments and optimize their design.

Conducting a failure analysis of the entire machine and all its subsystems can identify critical control factors. A few examples of the control factors in the Walkaway's transport and optic systems, their problem, and an improvement are given in Table 3.1.

Table 3.1- Control Factors, Problems, and Improvements

Control Factors	Problem	Improvement
driving mechanism torque	motor was oversized	smaller motor
CCD alignment	CCD adjustment very difficult	better adjustment design
lens magnification	image larger than CCD length	correct lens, CCD position
structure stiffness	cover does not engage	thicker structure or different material

Determining these critical values ahead of time would have improved the quality of the subsystems and avoided many problems. Future NPP projects should also allocate time to do an in-depth failure analysis.

It is necessary to first optimize the design and make the design robust, before doing Taguchi experiments. The Taguchi method is only a means of bringing the machine's capacity to its highest, but the design is what determines its ultimate capacity. The design of the receptor cup is an example of low robustness. Its design required the edge of the receptor cup to align with the inside wall of the carousel during assembly. A small draft angle was put on the wall of carousel to allow some play when aligning the receptor cup to the wall. This play was of .004 inches. Having to align the structure that contained the receptor cup and the carousel wall within .004 inches was not easy in the laboratory environment and will be even harder in the production line.

Manufacturing requirements

Because the NPP is a student project conducted at MIT and resources are limited, it is very difficult to have a manufacturing engineer represented in the PDT. Ideally, an experienced manufacturing engineer from the company would be part of the PDT. Since that cannot be the case, other means of impersonating manufacturing has to be devised. One possibility is hiring a student with some Manufacturing Engineering background. This student's responsibility would include familiarizing with the company's manufacturing capabilities and methods and their suppliers. This student would also be responsible for producing a Manufacturing Design Specifications (MDS), described in greater detail in Chapter 5, and ensuring that the proper attention is given to it throughout the development process.

The lack of a MDS in the Becton-Dickinson project allowed the PDT freedom to design parts which do not match Becton-Dickinson's manufacturing capabilities. These parts will either be sent to manufacturers outside Becton-Dickinson and increase the production cost, or suffer some re-design, which at this late stage is costly (see Figure 3.1). There are some examples in the Walkaway prototype where design for manufacturing and assembly (DFMA) is lacking in some parts. Some of these include:

- the optics structure cannot be injection molded in its current configuration;
- the transport structure is very large and will require an expensive tool and a large injection molded machine;
- numerous amounts of adjustments in the optics and between the subsystems;

- access to the lens adjustment is difficult;
- and, transport subsystem cannot be assembled in the current configuration.

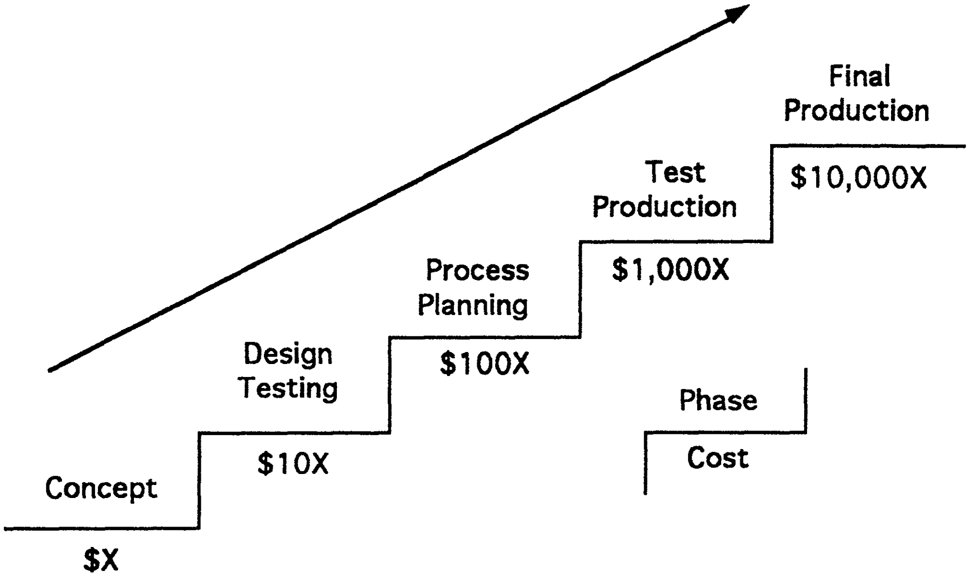


Figure 3.1. Cost of Design Changes in Each Development Phase (Port et al, 1990)

Building the Alpha Prototype and Integration

When a project is not planned properly, many problems arise during integration. During integration there is little time left to complete the project, not enough to fix large problems adequately and sometimes not even enough time to improvise a quick solution to make the prototype work. Unfortunately, in the Becton-Dickinson project this was also the case. Time expired before we could reduce the centrifuge noise to an acceptable level, or find a replacement for the linear variable filter. Many parts were taken back to the machine shop for changes. The cost for such changes are about 30% to 50% more than usual. For example, the arm and gripper subsystem was completely modified a few times in the span of one month. Many of these changes are difficult to avoid since they are merely common mistakes in drawing and in dimensions. However, some changes are due to not being able to foresee the problems when integrating the subsystems. Future NPP teams should try to avoid these types of modifications by constantly communicating and designing the integration of their subsystems with the other team members.

Many subsystems depend on the completion of other subsystems to undergo tests on their performance and to be optimized. If these other subsystems are incomplete or are suffering changes, the subsystems that are ready stay idle. When all the subsystems are finally integrated, there might not be enough time to fix the problems that arise. Though this scenario occurred in the Becton-Dickinson project, the outcome was not disastrous. The subsystems were integrated two days before the presentation and no complex problems arose, except for the vibration and noise levels of the centrifuge. However, some subsystems were ready many days before the presentation. The time that these subsystems remained idle, waiting for the completion of other subsystems, could have been used to conduct tests on the Walkaway or perhaps reduce the noise and vibration levels of the centrifuge.

Delays

The Becton-Dickinson project was exemplary in delivering the scheduled presentations on or close to their specified dates. However, this fact does not mean the project did not have its delays. The delays in the Becton-Dickinson project prevented the delivery of a better product. The consequences of delays in the project was the elimination of steps in the design process, such as Taguchi experiments, tests with the Walkaway, and debugging the Walkaway to void its problems. Delays stem from six sources (Zangwill, 1993), four of which were present in the Becton-Dickinson project. These were:

- failure to build technological foundations; the PDT had to invent and conduct research during the product development process, such as the linear variable filter, the light pipes, and the lens, previously mentioned in this chapter;
- failure to freeze specifications; for example, the disposal of tubes also previously mentioned;
- failure to properly monitor the project's progress and to quickly correct for any slippage; though the alpha phase was closely monitored in its early stages with the help of the CPM, as the tasks became delayed, this action was discontinued;
- failure to think through and plan the project up front; inadequate planning often results in failure to involve the right expertise, including, where

appropriate, suppliers, customers, and factory-floor workers; also, the up-front effort should include careful contingency planning and provide backup approaches. Compressing the design phase from eight months to five months is an example of inadequate planning and is a cause of delay.

The other two main sources of delay include, failure to provide adequate resources, and failure to get quick management approvals. Management in the Becton-Dickinson project was very diligent in providing resources and approval and there was no delay for these reasons. The NPP should continue providing this support to its projects. However, future NPP projects should also avoid the delays encountered in the Becton-Dickinson project. More suggestions for evading the causes for each delay are given in Chapter 5.

Chapter 4. An Improved Project Organization for the New Products Program

An improved project organization for the NPP is presented in this chapter, based on my experience in the Becton-Dickinson project. The overall organization of the NPP is composed of a self-directed, multi-functional team. Self-directed teams are a new trend in product development. They are teams that work under minimal supervision. The traditional "heavyweight" leader becomes more of a facilitator, "moving from umpire to counselor, from order-giver to project-reviewer." This project organization used by the NPP can be extremely successful if well implemented. Suggestions for achieving a better implementation of this organization is given in this chapter.

Section 4.1- Management

Kim Clark from Harvard University has studied the management of product development teams in automobile industry and concluded that most successful projects have a "heavyweight" director who manage the people and the project. According to Clark, the managers are not found in their offices, but with the people that they manage, always checking on the many details that are present in a project. "They have excellent knowledge of the project in order to balance the tradeoffs in suggestions that would enhance one aspect of the project while harming others (Zangwill, 1993)."

One of the goals of the NPP is to give the students in the PDT an opportunity to experience leadership in a product development project. The experience acquired by those involved in the Becton-Dickinson project is extremely invaluable. This leadership experience is one that cannot be taught in a classroom and should be continued in future projects. The NPP follows the self-directed team approach. However, each member of the PDT has different leadership abilities and it is important to always have a strong leadership in a project, whether it is done by one of the members or by the assigned leader. The NPP projects do not have to suffer from lack of leadership even if it provides inexperienced students with the opportunity to lead. The assigned project leader can ensure that the project maintains a strong leadership through constant supervision of each member's performance as the leader. If a student has a deficiency in the role, the project leader should aid that team member.

The characteristics necessary of top leaders include a simultaneous understanding of the many levels of the project. Projects fail because, though the strategy is well planned, technical details cannot be executed at the same level of competence as the strategy. On the other hand, though a team can have great technical capabilities, the lack of a good strategy will lead to failure. While few can even understand one of these levels well, the project leader has to be able to perceive how these different levels interact and how they reinforce each other for a successful project. They have to be skillful not only in the strategic planning of a project, but also in the different technical issues involved in the project. Top managers also understand the market and the competition. Most engineers involved in the technical aspects of a project, have little knowledge of the business side of the project. It is the duty of the project leader to direct the project with a more broad outlook of the product in the market and competing against products from other companies. This outlook has to be focused into all the detailed and technical decisions made throughout the entire development of the product. The NPP project leader should be carefully chosen and should have some of the characteristics described above.

It is important to note, however, that though management support is crucial, the support for wrong ideas will cause a product to fail. In a recent study of 125 companies, it was found that top managers supported failures with almost equal frequency as successes (see Figure 4.1). "Those projects where top management was committed, was involved directly in the management of the project, and provided considerable guidance/direction for the project were only marginally more successful. What we did find, however, was that top management support was important in driving products to market- in getting the project done. The message is that top management's main role in product innovation is to set the stage: commit to a game plan, and make available the right resources (Cooper and Kleinschmidt, 1990)." Table 4.1 lists some characteristics found in an effective team manager. The professor assigned to head a NPP project should meet as many of the requirements listed in Table 4.1 as possible.

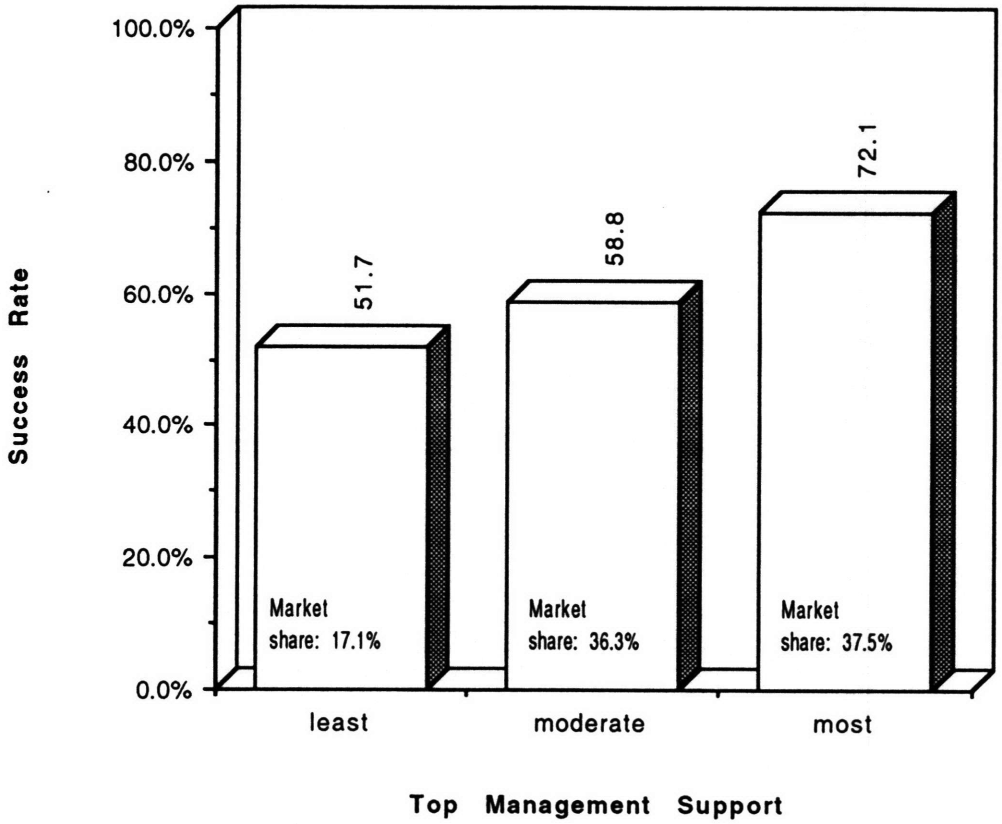


Figure 4.1. Effect of Top Management Support on New Product Success (Cooper and Kleinschmidt, 1990)

In summary, "innovative work groups have good leadership. That is, management understands the factors crucial to success and makes proper provisions. It is action-oriented, provides the needed resources, properly plans and directs the implementation of its programs and helps in identification and resolution of problems in their early stages (Thamhain, 1990)."

Table 4.1. Effective Product Leaders (Clausing,1993)

- has responsibility that is broad in scope and endures over the entire duration of the development program
- has responsibility for specifications, product concept, costs, and schedule
- has responsibility for ensuring that the product concept is accurately translated into technical detail.
- has frequent and direct communication with the PDT at the working level
- maintains direct contact with customers
- possesses multifunctional and multi-disciplinary abilities in order to communicate effectively with all relevant people.
- takes an active role in managing conflict; may initiate conflicts to prevent deviation from the original concept
- possesses market imagination, and the ability to lead in discerning the true voice of the customer
- circulates among the PDT and leads in achieving the winning product concept, rather than doing paperwork and conducting formal meetings.

Section 4.2- Formation of NPP Product Development Team

Every project starts with the formation of the product development team (PDT). Not long ago, companies were organized in teams of a specific field: a team of marketing, a team of industrial designers, a team of engineers, and a team of manufacturing engineers. Each phase of the design process was conducted by one team. At the completion of the phase, the results were "tossed over the wall" to the next team. If problems arose in manufacturing, the team would "toss it back" to the engineers who would try to fix the problem and pass it back to manufacturing. This sequential way of developing a product has become obsolete. It increases the product development cycle through iteration and causes many problems due to poor communication between the different teams.

The multi-functional team, also referred to as concurrent engineering team, was developed to solve this problem. A multi-functional team is composed of members from every department involved in the project at any of its development stages. Thus, the minimum requirement for a multifunctional PDT is of marketing, industrial design, engineering, design, manufacturing, and management. Other more specific fields may or may not be part of the PDT according to the nature of the product. In the NPP, the number of team members is limited by the funding allocated to the project. In a $500,000 project, over a period of two years, the number of graduate students that can be hired for the project is restricted to approximately four. Thus, it is necessary to optimize the "multi-functionality" of the team. This can be best achieved by hiring students with multi-functional backgrounds. In the Becton-Dickinson project, for example, one student with both electrical engineering and computer science background was able to be responsible for all systems in those fields, including controls and electronics. A possible example of a future NPP team core could include:

- electrical engineering and computer science graduate student;
- mechanical engineering design and manufacturing engineering graduate student;
- mechanical engineering design and Industrial design graduate student;
- and, a marketing and another specialized field depending on the project graduate student.

This would encompass the essential disciplines necessary to support a project. Senior level undergraduate students could also help the graduate students in particular areas.

A multi-functional team, though not the only important criteria for a successful project, is an essential step in the development of a new product. Without a multi-functional team, the NPP projects could suffer longer development cycles and produce poorer quality prototypes.

The criteria for group formation

In the NPP, the formation of a good PDT for each new project is a very difficult task. In most companies, managers who form a team have worked with some employees, and can form a good team based on this background knowledge. Because a new group is formed for each NPP project, there is little knowledge of how well the students will perform as a team. The best attempt is to select students based on good academic record, work experience, and perhaps some knowledge about that student through classes or through recommendations from other professors, fellow classmates, or former employers. When selecting the team members, the project manager has to be aware of the principles that compose a successful team. These are listed in Table 4.2 below.

Table 4.2. Ten Principles of Successful Teams (Morley, 1990)

- Select cohesive team members, based on sentiments of mutual liking and respect for each other's expertise.
- Bring specialists from all major functional areas into the PDT
- Ensure members have a common vision of the concurrent process
- Organize controlled convergence to solutions which everyone understands and accepts
- Organize vigilant information processing and encourage actively open-minded thinking. Avoid facile, premature consensus.
- Maintain the best balance between individual work and group work. Let individuals do the things that individuals do best; for example, the initial generation of new concepts.
- Use systematic methods.
- Use both formal and informal communication.
- Select at least some of the members to be especially well suited to the type of development work. One example is the static/dynamic conceptual characteristic of the work. A member who is proficient in utilizing standards to rapidly complete static designs may have difficulty with dynamic conceptual work. The opposite is also true.
- Provide principled leadership. The leadership must emphasize the improved process, making it visible to the team. The leadership must take primary responsibility for helping to empower members of the team.

Since the selection of team members for a NPP project is difficult, it is also difficult to ensure that the PDT will have the qualities listed above. However, some of these criteria can be improved even those that seem uncontrollable, such as "there should not be any sudden changes in the composition or size of the PDT, as that would reduce teamwork and cause lack of continuity (Clausing, 1993)." It is impossible to avoid graduate students from graduating and leaving the project. Since the typical NPP project lasts two years, it is probable that no team member will stay throughout the duration of the project. To ensure constant composition of the PDT and proper information transfer from the departing student to the incoming one, the project leader must hire a new student many weeks before one leaves. During this time, the departing student should transfer all of his/her information to the replacement. When the student finally leaves, the new replacement will need to spend no time updating him/herself to the project and to his/her responsibilities. Thus, the project loses no momentum or continuity. During this overlapping time, the new student can also work on becoming part of the team.

It is extremely important to work on team building throughout the entire duration of a NPP project, especially in its initial stages. The project leader has to be constantly monitoring feedback from the PDT and avoid or resolve problems at an early stage. There are many indications that can serve as early warning signs of problems with the PDT performance. They are listed in Table 4.3.

Table 4.3. Early Warning Signs of Problems with PDT Performance (Thamhain, 1990)

- Project perceived as unimportant
- Unclear task/project goals and objectives
- Excessive conflict among team members
- Unclear mission and business objectives
- Unclear requirements
- Perceived technical uncertainty and risks
- Low motivation, apathy, low team spirit
- Little tea involvement during project planning
- Disinterested, uninvolved management
- Poor communications among team members
- Poor communication with support groups
- Problems in attracting and holding team members
- Unclear role definition, role conflict, power struggle
- No agreement on project plans
- Lack of performance feedback
- Professional skill obsolescence
- Perception of inadequate rewards and incentives
- Poor recognition and visibility of accomplishments
- Little work challenge (professionally not stimulating)
- Fear of failure, potential penalty
- Fear of evaluation
- Mistrust, collusion, protectionism
- Excessive documentation
- Excessive requests for directions
- Complaints about insufficient resources
- Strong resistance to change

It is unclear of how some of these problems may affect the outcome of the project. Thus, an effective leader should be aware of all potential and actual problems and minimize them whenever possible. "The effective manager of a team is usually a social architect who understands the interaction of organizational and behavioral variables and can foster a climate of active participation and minimal dysfunctional conflict. This requires carefully developed skills in leadership, administration and organizational and technical expertise (Thamhain, 1990)." In the Becton-Dickinson project, conflicts within the team were present and were never resolved. This hindered communication and cooperation in the team. Future NPP project leaders have to encourage the PDT to expose all problems and other team members have to help solve the conflicts as they arise.

Section 4.3- Creating a Good Strategy

A pivotal step in the development of a new product is to define the target market, product concept, development process, product requirements and benefits to be delivered, all of which become the product strategy. The product strategy must be determined before development of the product begins. The lack of a good strategy is one of the main causes for the failure of new products. In a recent study, one of the key factors underlying success was "a well-defined product and project prior to the development phase (Cooper and Kleinschmidt, 1990)." According to that study, products with a sharp definition were 3.3 times more successful than those with little or no definition, as shown in Figure 4.2. "What is required is an explicit structuring and ordering of these activities into a coherent process (Page, 1993)."

In another study of 360 managers in 52 high technology companies, it was identified that the strongest association to innovative performance relate to clear objectives, directions and project plans (Thamhain, 1990). There are many tools for explicit organization and planning of a project, such as Gantt Charts, Program Evaluation and Review Technique (PERT) and Critical Path Method (CPM). The Becton-Dickinson project used the CPM and was successful in its planning. Future NPP projects can imitate Becton-Dickinson's success by using the CPM. The CPM has the following practical applications (Slocum, 1992):

- provide a means to demonstrate that initial time estimates were wrong, and help give a more realistic estimate of the time required to complete the project;
- focus attention on potential problems that might arise in the development process;
- ensures that team members keep to their commitments;

- avoids potential misunderstanding and miscommunication among team members;
- allows quick adjustments of the project schedule due to unforeseen changes or problems;
- and, give a small overview of what the development process for the new product will be like.

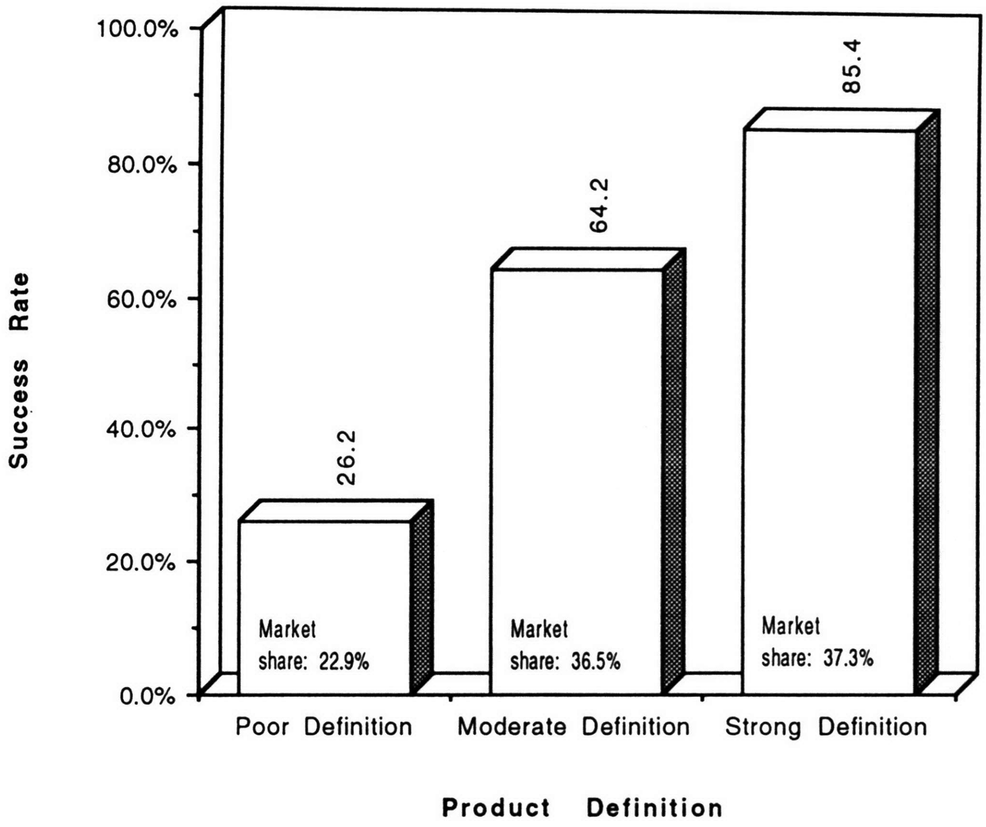


Figure 4.2. Impact of Early Product/Project Definition on New Product Success (Cooper and Kleinschmidt, 1990)

In the Becton-Dickinson project, there was little time left for the construction of the Walkaway alpha prototype. To avoid such situations, at the start of each NPP project, the PDT must roughly plan the entire project. A estimate of time must be allocated to each phase of the project. For example, a two year project could be divided into 5 months for market study, 3 months for concept generation/selection, 8 months for the construction of the first prototype, and 8 months for the construction of an alpha prototype. Once the entire project is roughly divided, meetings and presentations between the sponsoring company and the PDT can be scheduled at the end of each phase. This rough plan can be subject to changes but it allows the PDT to have a better idea of how much time is allocated to the each phase.

Once the entire project is roughly planned, the first phase should be planned with a greater level of detail. It is critical to pay attention to the level of detail in forming this plan. The level of detail is very important because if the small steps within each phase are not explicitly determined, most team members will not follow the same process. More detail in the CPM also ensures a more accurate estimate of time for the completion of a particular task, therefore improving the overall estimate of the entire project. For example, a time of one month can be allocated for "market study" and all members of the PDT can be in agreement. However, "market study" can be broken down into: conducting interviews, performing image KJ's, completing Kano questionnaires, and filling the House of Quality. If each step takes more than one week, our original estimate for market research of one month is already incorrect.

There are two other benefits in creating a detailed plan. First, the PDT can make a more realistic estimate of how long each step will take, such as noticing that one week might not be enough for the completion of the House of Quality. A more accurate estimate of each step will also help the PDT to maintain the schedule. Second, in making a detailed plan, the PDT will realize all the necessary steps it will take to complete a phase. For example, to conduct the market study it will be necessary to go through all the steps explicitly shown in the plan: personal interviews, image KJ, Kano questionnaires, and House of Quality. Again, a deeper level of detail in the planning will allow project manager to verify that the PDT is conducting a thorough market research and not "cutting corners". This detailed plan should be made at start of each phase in the design process.

Too much detail, however, is not productive when planning a new project. Going into detail of how to perform certain steps, such as completing a House of Quality, is not the goal of making a plan and should not be part of a CPM. The CPM should give a detailed overview of all the main steps in the development process but not describe the actual method for completing each step. It is assumed that most members of the PDT will have an idea of what completing a House of Quality entails. The details of how to complete a House of Quality should only be reviewed by the PDT just before the beginning of that task and not during planning. It is then that all members of the PDT who did not know much about a task or had little experience actually performing a task, learn and understand that step thoroughly. Thus, the time the entire PDT spends in making a project plan is not too extensive; and, before performing each task, the PDT will have equal knowledge of the exact steps needed to complete that task. In the Becton-Dickinson project, for example, the PDT should have had a meeting before beginning to complete the House of Quality. The PDT could have outlined and discussed the many steps necessary to complete it. This would have generated a better understanding of the tool, and perhaps its results could have been better utilized.

Chapter 5- An Improved Design Process for the New Products Program

"To be successful, you have to be systematic and thorough, paying meticulous attention to detail from the beginning to the end of the total design activity."
- Stuart Pugh

The importance of following a good design process are many. A defined process increases the effectiveness of the team. A process organizes the different stages that the development team goes through, creating a new product in a flowing manner. It reduces the cycle time for the development of a new product by reducing the number of iterations performed within each phase.

There have been many design processes formed throughout the past few decades. However, in the quest for improvement of product development, many companies have modified the design process to reduce the cycle time and improve the quality of the product. In the 80's, Japanese companies dominated many markets simply because they had a better product at lower cost. They achieved this by incorporating into their company new design processes that focused on a successful product. These more advanced design processes were sparkled by the philosophy of *continuous improvement*. This philosophy, when applied to the design process itself, will produce a better product with superior quality. Design for continuous improvement, for example, does not try to fulfill a specification such as making a product within certain size limits. Continuous improvement means trying to make the dimensions as small as possible. The

NPP should always try to follow the continuous improvement design philosophy.

The new design process of the NPP focuses on producing a high quality product through continuous improvement and reducing cycle time by eliminating iteration and designing the product well the first time. However, the development of a successful product involves more than just following a process. There are many other criteria such as team formation and project management described in the previous chapter, that influence the success of a product.

"There is no substitute for knowledge. Everyone doing their best is not good enough. It is first necessary that people know what to do."
- W. Edwards Deming

The first step in the design process is to have the PDT fully understand the process they are about to follow. Without a good grasp of each step necessary to develop a new product, the PDT will have more problems. A step poorly taken can generate severe consequences such as delays or poor design. In the Becton-Dickinson project, for example, the House of Quality was not properly completed and could have led to poor product specifications. This, in turn, could lead the design team to focus on the wrong characteristics of the product. Based on the Becton-Dickinson project, the following sections will describe in greater detail a possible improvement for the NPP design process.

An overview of the new NPP design process

At the beginning of each NPP project, it is very important to explicitly describe the design process to the entire PDT so all members are fully aware of what needs to be accomplished for the product to be successful. To be able to develop a successful product, the NPP PDT should avoid obstacles that make a project fail. Studies have identified many of these obstacles, some of which were present in the Becton-Dickinson project. The PDT should pay special attention to the obstacles to a successful product development listed in Table 5.1.

Table 5.1 Obstacles to Successful New Product Development (Page, 1993 and Clausing, 1993)

Clever technology but no need for it.
Disregard for Voice of the Customer.
Only one concept is given serious consideration.
Development through iteration of prototypes.
Disregard for manufacturing.
Disregard for new ideas.
Team isolation.
Target oriented as opposed to continuous improvement.
Inspection as a means of eliminating imperfections.
Solving problems as they arise as opposed to making a product problem-free.
Lack of top management support.
Poor organization.
Bureaucratic nature of the organization.
Poor people resources/support
Poor communication.
Little time available to do product development work.

Over the past decade, many new design processes have been developed, including Total Quality Development (TQD), Design For Manufacturing and Assembly (DFMA), Lightning Strategies for Innovation, Total Design, and Enhanced Quality Function Deployment (EQFD). The design process used in the Becton-Dickinson project was basic Concurrent Engineering. Though this method was very successful in producing an alpha prototype that was very pleasing to the Becton-Dickinson management, it also contained problems, many of which can be solved with an improved design process. In the following sections I suggest a new process to be followed, which is based on Total Quality Development (Clausing, 1993) with a few changes and additions from some of the processes mentioned above. Based on my experience in the NPP and with Total Quality Development, I believe the NPP will have even greater success with the proper execution of this process. I will refer to this process as the *new NPP design process*.

The new NPP design process contains three main phases, each distinct from the others. These are:

- conceptual phase,
- design phase,
- and, production phase

The *conceptual phase* has three main functions. It brings the voice of the customer in the context of the product strategy, develops the product concept (including new technology to be used), and deploys to design requirements that are responsive to the customer and to the corporate strategy. In the *design phase,* the product concept is developed into a complete and detailed production-intent design. In the *production phase*, prototypes are built, tested, and debugged.

Section 5.1-Conceptual Phase

The voice of the customer

The first step in the conceptual phase is identifying the customers and bring in their "voices". The product strategy determines which market segment to target and what customers to interview. There are many methods for obtaining the voice of the customer, but it is necessary that this voice be unbiased and true. Once the voice is obtained, they have to be clarified, structured and prioritized. There are a series of steps necessary to obtain the voice of the customer. Typically, first contact with the customer is obtained through qualitative interviews with customer, in person or by telephone. There have been many successful methods of obtaining the voice of the customer. The PDT in the Becton-Dickinson project was very effective in obtaining the voice of the customer. The current method for market study in the NPP can remain almost the same as in the Becton-Dickinson project. For greater detail, the reader is encouraged to read the Richard Wong's Masters thesis (Wong, 1992)

Although there are many other ways one could do a successful market study, the PDT must be very careful before substituting any other step in this design process. Thorough attention to the many details of the design process and structured methodology are key factors in a successful project, and the PDT should be certain that substituting steps in this design process will only generate improvement.

Focus groups was also performed in the Becton-Dickinson project to obtain the voice of the customer. In a recent study by Honda and Mazda, they have discovered that about one-third of the conclusions learned from focus groups are wrong (Zangwill, 1993). These companies noticed that the information customers were stating differed from the data obtained from facial muscle. Companies are putting sensors on the customers' faces and allowing them to test their products, thus collecting more accurate data and getting in closer contact with their emotional responses. In the Becton-Dickinson project, although the PDT gained further insight of the blood analyzer market in the focus group, given its questionable results, it could be a step eliminated from the market study.

Image KJ

In addition to the current market study techniques used by the NPP, image KJ and Kano questionnaires can be incorporated. These two techniques could generate a greater understanding of the customers and prioritize their "voices". These techniques and all others in this chapter are described very briefly. The reader, if not familiar with them, is encouraged to find out more about them through more detailed literature.

Like in the Becton-Dickinson project, interviews should be done with the entire PDT involved. The data obtained in these interviews could be used to complete an image KJ, which was developed by Jiro Kawakita. The image KJ is a tool that structures detailed data into more general conclusions. It is used for providing initial structure in problem exploration. One of the most helpful characteristics of completing the image KJ is the many discussions that center around each image. This will quickly get the entire PDT knowledgeable of the many aspects involved with the product that they are about to develop and will become the basis of common understanding about the customers and their perception of the product.

Multi-Pickup Method

At the completion of the interviews, many images are generated, sometimes hundreds depending on the complexity of the product. It is extremely important to select the most important images. A very effective selection process is the Multi-pickup method (MPM) (Shiba et al, 1993). This selection process emphasizes strength as opposed to eliminating weakness. MPM is not just voting. Each team member marks one choice in turn. A second or third round of choices can be made if more choices are necessary. MPM is done in stages, beginning with a discussion of the theme, followed by an unconstrained selection by all team members, and ending with a focused pickup, where each team member has a limited amount of choices. Between each stage, there can be a small discussion on the choices left. The MPM is a very useful tool and can be used throughout the design process, especially when selecting the most important “voices” to complete a House of Quality.

Kano Questionnaire

When the image KJ is complete, a list of customer requirements are formed from the image KJ. These customer requirements are compiled into a Kano survey. This survey is sent to the same customers that were originally interviewed. The results of the survey are used to confirm and prioritize the voice of the customer. The Kano model was conceived by Noriaki Kano, and it is based on the observation that from the customer's view a product has three types of features:

- *presumed*- the ones the customer assumes the product will have and pays little attention;
- *expected*- the ones the customer examines in the buying decision;
- *delight*- the ones the customer does not expect and that sell the product.

Based on this theory, the Kano survey is sent to the customers to identify the features that customers “presume, expect, or delight.” From the results of the Kano survey, the PDT can rank the customer requirements and select the most important ones.

House of Quality

Once the voice of the customer is obtained and ranked, it is necessary to translate these voices into quantitative product specifications. The tool used in the Becton-Dickinson project is the House of Quality. There are many steps to filling a House of Quality, yet I will only mention the most important ones and the ones that could have been improved in the Becton-Dickinson project. For further detail, the reader is encouraged to read more on the House of Quality (Hauser and Clausing, 1988).

It is crucial to limit the number of voices of the customer to about twenty, but not more than thirty since this will focus the development effort on voices that will truly make an effect on the success of the product, and it will also make the House of Quality more manageable to complete. After the voices of the customer have been prioritized using the Kano questionnaires the most important ones can be selected. In the Becton-Dickinson project, the number of voices were too large and that had many consequences, including lost time, effort and information. The House of Quality was never finished and this prevented the team from deploying the results down to the other stages of the Walkaway.

The next important stage is comparing competitor's products in the main categories. This benchmarking will allow the PDT to determine quantitative values for the product design specifications. It is important to identify the breakthrough levels of performance, the levels of product performance in the prime voice of the customer categories that beat the competition by satisfying the customer better. These levels should be specified as the Product Design Specification (PDS).

Product Design Specification

The outcome of the House of Quality should be a Product Design Specification (PDS) (Pugh, 1991). The PDS is an extremely important document. It is the fundamental control mechanism that allows a successful project. It achieves this goal through systematic and thorough design, with meticulous attention to detail from beginning to end. It is used as the basic reference throughout the development process. The absence of a PDS can lead to poor designs and unsuccessful products. A good PDS will not necessarily result in a successful product, but it will make that goal attainable. Therefore, "the PDS has to be comprehensive and unambiguous. If an experienced designer of the PDT is asked to design something with a less than comprehensive PDS, he/she will almost, without thinking, fill in the gaps based on his or her experience and feelings; if these happen to be at variance with the true user needs, he will be designing to the wrong base." (Pugh, 1991) Table 5.2 lists the many elements of the PDS. The NPP PDT should attempt to complete all the elements of the PDS with particular attention to the engineering constraints determined using the House of Quality. These constraints will be directly copied into the PDS. Information for the completion of all other elements that were not addressed in the House of Quality should be based on the knowledge that the PDT gathered throughout the collection of the voice of the customer. Once complete, "the PDS sets the design in context, representing as it does a comprehensive set of constraints which are always in a unique combination."

Table 5.2. Elements of the PDS (Pugh, 1991)

Patents
Quality
Reliability
Packing
Competition
Maintenance
Weight
Politics
Disposal
Quantity
Legal
Shelf life Storage
Market Constraints
Company Constraints
Standard Specifications
Product Life span
Documentation
Time scale
Product Cost
Life in Service
Environment
Manufacturing Constraints
Shipping
Size
Processes
Customer
Performance
Installation
Aesthetics
Ergonomics
Materials
Safety
Testing

Progressive Freeze

The completion of the PDS marks the end of a very important stage. At this time, it is important to have a progressive freeze. The progressive freeze is a unanimous agreement by the PDT on a particular decision. From then onward, the PDT will not address or modify that decision, unless unforeseen changes force the PDT to reconsider their decision. Freezing is very important throughout the design process as it avoids dysfunctional repetition. It is necessary to have progressive freezes at the completion of each major step, such as the completion of the PDS. No team member should reconsider the decision once it is made, unless it is induced by some uncontrollable and unforeseen event, for example, in the Becton-Dickinson project, the threat of a new Health Care reform in the United States completely changed the customer specifications for the Walkaway.

From Total Quality Management, a technique to do a progressive freeze is a "yo-one" ceremony. The mechanics of the ceremony are simple: once the PDT has reached agreement of closure, all team members stand in a circle so they all can see each other. One member starts by saying "yo-oh". The rest of the PDT join in, and then the group says the word "one" in a louder voice and clap their hands simultaneously. The yo-one ceremony signifies completion and agreement. It is a mutual understanding that each team member is unambiguously committed to making their work or their decision final. (Shiba et al, 1990) Performing a yo-one ceremony at the end of the House of Quality and the completion of the PDS will allow those two documents to be used as the main reference and foundation for the product design. It is important to have this solid foundation in the NPP projects, upon which a successful prototype can be built.

The Manufacturing Technical Specifications

It is important to tie design to manufacturing at an early stage. Merely having a student with manufacturing engineering background as a member of the PDT is not enough. It is essential to have a more formal method of ensuring that the NPP will incorporate manufacturability characteristics into its final prototypes. This can be achieved by establishing manufacturability requirements, or a Manufacturing Design Specification (MDS). The MDS are quantified statements about the configuration, cost or performance of the manufacturing systems what will eventually fabricate and assemble the product. The MDS are a series of instructions to the PDT from manufacturing, such as imposing process capability limits, specifying facilities and equipment, and limiting part geometry. Similar to the PDS, the MDS should be a formal document with quantified detail of all requirements. The PDS has to be in balance with the MDS (see Figure 5.1).

Total System Concept Generation

The next stage in the design process is concept generation for the new product. This was also a very successful stage in the Becton-Dickinson project. It is detailed in Don Lee's thesis (Lee, 1993) and does not need to undergo many changes. Below, I emphasize the usefulness of the Pugh chart, its strengths and its pitfalls.

Throughout the previous stages, every team member had many concepts generated in their own minds. Although most of the work in the development of a new product is done in a team, brainstorming should be done

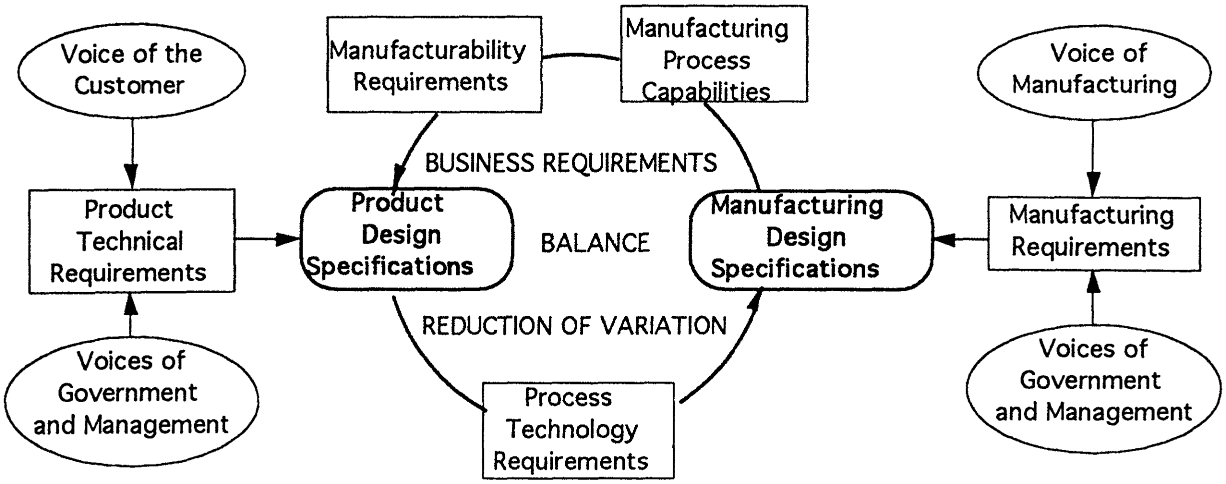


Figure 5.1. Development of Design Specifications (Rampenthal, 1993)

individually at first. It has been shown that brainstorming and concept generation is more productive individually since the ideas generated by other team members only hinder new ideas from being generated. Once the PDT agrees that they have brainstormed enough, all the ideas generated have to be organized for selection. First, repeated ideas should be combined. Then, the PDT has to agree on the number of concepts they would like to consider seriously. At this time, a MPM could be performed to select the concepts that the team consider best. The preparation stage of the MPM should include a review of the PDS and MDS and a brief explanation of all the concepts generated by each member. Once the number of concepts has been decreased to a manageable amount, the PDT can run a Pugh concept selection process.

The Pugh concept selection process is a very helpful tool, not only in concept selection, but also in generating improved concepts. It is a tool that generates new concepts through discipline and insights. Usually, the chosen concept is never one of the original concepts, but a hybrid or combination of many other concepts. As one completes the Pugh chart with positive and negatives, the strengths and weaknesses of each concept becomes apparent. This allows the PDT to new insights on how to avoid the problems and use the strengths of different concepts; therefore modifying the original concepts for better ones. The PDT should be aware that the Pugh selection process is not only a tool for choosing the best concept, but also an iterative aid in concept generation.

The first step in making a Pugh chart is selecting the criteria with which each concept will be compared. The criteria must be heavily based on the PDS, the MDS, and the engineering constraints from the House of Quality. This is one of the ways the voice of the customer is deployed to the design of the product. Using the voice of the customer as the selection criteria, the best concept will be generated and chosen. The PDT must first have a discussion on the most important criteria from those sources and perhaps add or subtract criteria as they see most appropriate. Each criteria should be clear to all the members of the PDT.

Another important step in the Pugh selection process is attacking the negatives and enhancing the positives of all the original concepts. It is trying to eliminate all the negative marks from each concept that the original concepts are modified and improved. The Pugh chart is run again with these new and improved concepts. This iterative process will finally end with one winning concept. This process may not always run so smoothly. Many times, there is not enough information on the new concepts to make a good evaluation related to the criteria. In this case, before the Pugh matrix is run, the PDT should spend time gathering all the missing information on the new concepts. Sometimes this may even involve doing some tests and experimentation. The Becton-Dickinson PDT encountered this situation. Many concepts were generated for tube reading. However, insufficient information on the concepts forced the PDT to do some research and experimentation. This was thoroughly done by the PDT and once enough information was gathered, the PDT concluded that the Charged Coupled Device (CCD) was the best selection. This process of selection was well performed and it is apparent in the results of the project. The CCD in the Walkaway is very robust and suffered no changes between the first prototype and the final alpha prototype. Future NPP should try to imitate the concept selection steps performed for the CCD. Guessing the level of a concept in one criteria can prove to be harmful in the future, and must be avoided. For example, guessing that a difficult to manufacture concept can be easily fabricated will alter the entire design once the discrepancy is discovered.

The final outcome of this stage should be one: a successful product concept. It is the one that best fulfills the customer requirements while satisfying manufacturing specifications. It is expected that once the concept is developed into a finished product, this product will become the competitive benchmark against which all other products will be compared. The concept should be thoroughly described and detailed on a document, including figures, so the PDT will not have any discrepancies among themselves of how the final product will perform or what its layout will be. This document will be used as a reference throughout the next phases.

At this time, the selection of all technological concepts for each subsystem or major functional area should be frozen. "The technological and research foundations should be complete because the lack of any crucial technology can devastate a project." (Zangwill, 1993) If new technology is being used which differ greatly from any technology used by the PDT before, it is important to make sure that the technology is sufficiently mature. The technological concepts that have been chosen give every reason to believe that they will meet all product expectation specifications, and that after completion of optimization they will be world leaders in cost and performance. This can only be confirmed if the new technology is tested at near nominal conditions (Clausing, 1993). It should also be clear that the new technology is manufacturable according to the MDS.

The facts show that product development teams cannot easily work with newness and keep to their schedules. "Engineers need new ideas that snap into the skills they already have. They want to use the tools they've already mastered. Product development has a timetable that cannot be interrupted to accommodate some unexpected piece of technology. New solutions, however sweet, have to be available to designers at the beginning of the cycle. Halfway through is too late. Even at the start of the cycle, new ideas are useful only if they've been pretty well fleshed out and tested so that the development team can incorporate them without breaking stride" (Gomory, 1989).

At this stage, it is necessary to have a design review with the upper management from the sponsoring company, and present them the work that has been done throughout the concept phase. Upper management should be shown all the market research performed and how the chosen concept will fulfill all the customer expectations of the new product. When management has been pleased with the work so far, it is good to perform a yo-one ceremony. The PDT and the company is in agreement that the product concept is a winner. In this case, the visiting management can also participate in the ceremony as proof that the PDT should not hesitate in the development of the concept into a successful product.

Deployment

In this stage, the total concept specifications are deployed into subsystems. The first step is the division of the total concept into smaller subsystems. There is no universal way to do this, and it is very product-dependent. The division should be intuitive and done as a group. For example, a car can be divided into engine, chassis, and interior. Interior can be further divided into driver related systems or passenger related systems. Driver related systems can also be divided into passive systems (displays, etc.) and active systems (steering wheel, pedals, etc.). To what level of detail the concept should be broken down to is decided by the PDT. One criteria should be that the subsystem be manageable by the designer or team of designers.

Once the subsystems have been determined, an "abbreviated" House of Quality is made for each subsystem. These small Houses of Quality are tools for dividing the total design specifications into each subsystem to ensure that the voice of the customer is being spread to the detailed levels of design. Thus, at the end of this stage each subsystem will have its own set of requirements which meet the expectations in the PDS. This stage also enables each member of the PDT to be aware of what every subsystem has to do, without any room for ambiguity. The voice of the customer is deployed to the subsystem level by using the engineering requirements as the input row for each subsystem House of Quality. Only the relevant engineering constraints are used for each subsystem House of Quality. These total system engineering constraints are translated into subsystem constraints just as it is done in the voice of the customer House of Quality. The final result is a quantitative list of subsystem constraints which are based on the original voice of the customer.

This marks the end of the conceptual phase. In the design phase, each team member is about to embark in more individual efforts. It is crucial that all members are fully aware of the responsibilities of all other members. The subsystem specifications give them this security. With this consensus, the PDT can do a yo-one ceremony and move to the next phase.

Section 5.2- Design phase

The design phase has three functions: to define the values of the critical design parameters, make early decisions on the most important piece part requirements, and complete the detailed design of all piece-parts. As in other phases, there are a series of methods that can be used to perform these functions. As mentioned before, the PDT might want to take shortcuts especially if behind schedule. This should not be done. It will only make the process less thorough and result in late changes and iteration at a high cost. Variation from the suggested design process should only be done at the highest level of detail, such as substituting the Multi-pickup method (MPM) for another selection tool. The PDT, however should not alter the more basic steps in the design process, such as completing the House of Quality. Although careful attention to these many steps might seem time consuming, the PDT should always remember that time spent at these early stages will be beneficial and profitable in the later stages.

Failure Analysis and Control Factors

The first step in the design phase is to identify the critical design parameters. This can be accomplished with the help of relational networks such as the fishbone cause-and-effect (Ishikawa) diagrams. A useful tool is failure analysis. Failure analysis, which includes fault tree analysis (FTA), functional tree, and failure mode and effect and analysis (FMEA) are tools used to identify the critical design parameters. These parameters are optimized to achieve robust functionality. Failure analysis is a tool that predicts different events and combination of events which may cause functional failure in the product or human injury. The purpose of this analysis is to avoid failures during regular or irregular use of the product by taking appropriate precautions during the design and production phases. Although it is not necessary to do use all three tools in failure analysis, doing them all will generate more accurate results.

The Fault Tree Analysis (FTA) defines unwanted conditions of the system, and by logical means detect which events, component failures, or operations may cause a system failure or hazard (Holt, 1988). At the bottom of the FTA are the critical parameters, both control factors and noise factors. The noise factors could be three: variations in conditions of customer use, production variations, and wear or other deterioration. At this point, the subsystem requirements are deployed to piece-part requirements using another "abbreviated" House of Quality. The input rows, in this case, are the subsystem requirements (which were the columns of the subsystem House of Quality). Again, the voice of the customer continues to deploy into the most detailed levels of the design. The piece-part requirements are virtually the control factors and noise factors determined using failure analysis.

The Becton-Dickinson project did complete a FMEA, but did not make full use of its results. The work done by the PDT could have been further developed to identify the critical parameters and optimize them.

After the identification of the control factors, the next task is to determine the best values for these control factors in order to optimize the functionality of the product, making it less sensitive to the noises. Selecting these values is done using parameter design, also known as the Taguchi method.

Taguchi Method and Benchmarking

Basically, the Taguchi method is a series of well designed experiments that lead to obtaining optimized levels for the control factors. It is extremely important to ensure that the experiments being run imitate the conditions seen by the final product. In setting up the breadboard experiments, the PDT should try to produce hardware with the same characteristics as that of the final product. Deviations from this condition will make many of the results from the experiments invalid. Once the values are obtained, they are inserted into the piece-part House of Quality.

The Becton-Dickinson project did not have time to perform the Taguchi experiments. Future NPP should ensure that enough time is allocated in the development process to do these experiments. Given more time, such experiments could have been performed in the centrifuge mounts of the Walkaway. The results would determine the ideal number and flexibility of the vibration mounts to be used in the Walkaway prototype.

There are another set of input values necessary to complete the piece-part specifications. These values are set by performing competitive benchmarking. The main function of competitive benchmarking is to be able to design low-cost, manufacturable, competitive products. This is achieved by comparing the chosen concept to the best practice in the world, and beating its cost in every subsystem. Thus, it is necessary to first quantify the cost for each function performed by the benchmark product. This is achieved by breaking down the product into its main functions, using a functional tree, and associating those functions with the cost of all the pieces that perform that function. This list of parts is called a hardware tree. The PDT is challenged to beat the cost of each of those functions. These values become the final input of the piece-part requirements House of Quality.

"Know your enemy and know yourself; in a hundred battles you will never be in peril."
- General Sun Tzu, "The Art of War"

Robustness is crucial in the integration of the many subsystems. The lack of robustness in a subsystem makes it sensitive to noises. During integration of subsystems, many noises are introduced into the subsystem, causing them to be reworked and extending the development time. Robustness will also make manufacturing and assembly easier. A robust subsystem will be less sensitive to variations in the manufacturing processes, thus the tolerances of the many manufacturing processes involved will be considerably looser. This is problem prevention at its best. The NPP PDT should attempt to produce robust prototypes, which can be manufactured and operational under extreme conditions.

Design reviews

Explicit design reviews can eradicate many potential problems through the design phase. At key stages of each member's work, the PDT should check their design of the systems and major components. Phil Walker, Motorola executive, declares that design reviews are "critical". During the rush to get projects finished, teams have a tendency to skip the reviews, but Motorola insists they be done. Some companies use "designer's scorecard" to judge the progress of the team member. (Zangwill, 1993) The scorecard should be based on the PDS and MDS to ensure that the review thoroughly examines the crucial aspects of the product development.

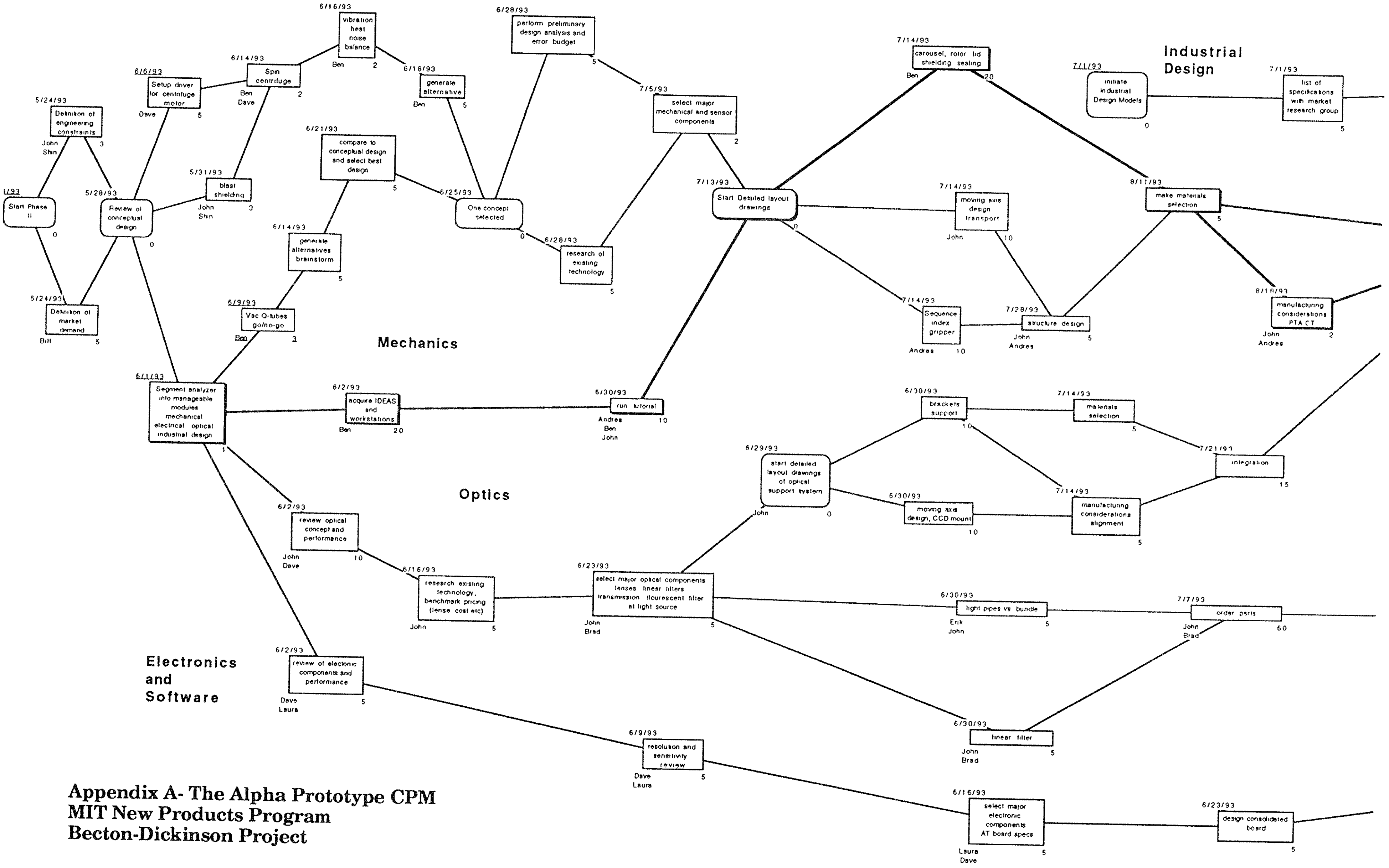
The purpose of the design review is not to criticize the work performed by the designer, but to act as a source of good ideas in order to achieve an even better design. It presupposes that the PDT together possesses more technical knowledge than the individual designer. This eliminates the need for a "blind trust" between team members. It also allows all team members to be updated with all other subsystems, and detect and remedy deficiencies in integration. This “early warning” concept is essential to avoid problems in the late stages of the design process. The reviews should be frequent and regular. In the Becton-Dickinson project, meetings were held weekly to update the PDT on each member’s progress. Though this was successful in keeping the entire PDT informed of its progress, a more aggressive design review could have improved the design and integration of the different subsystems. To avoid extensive meetings, an agenda and documentation could be prepared in advance.

Section 5.3- Production Phase

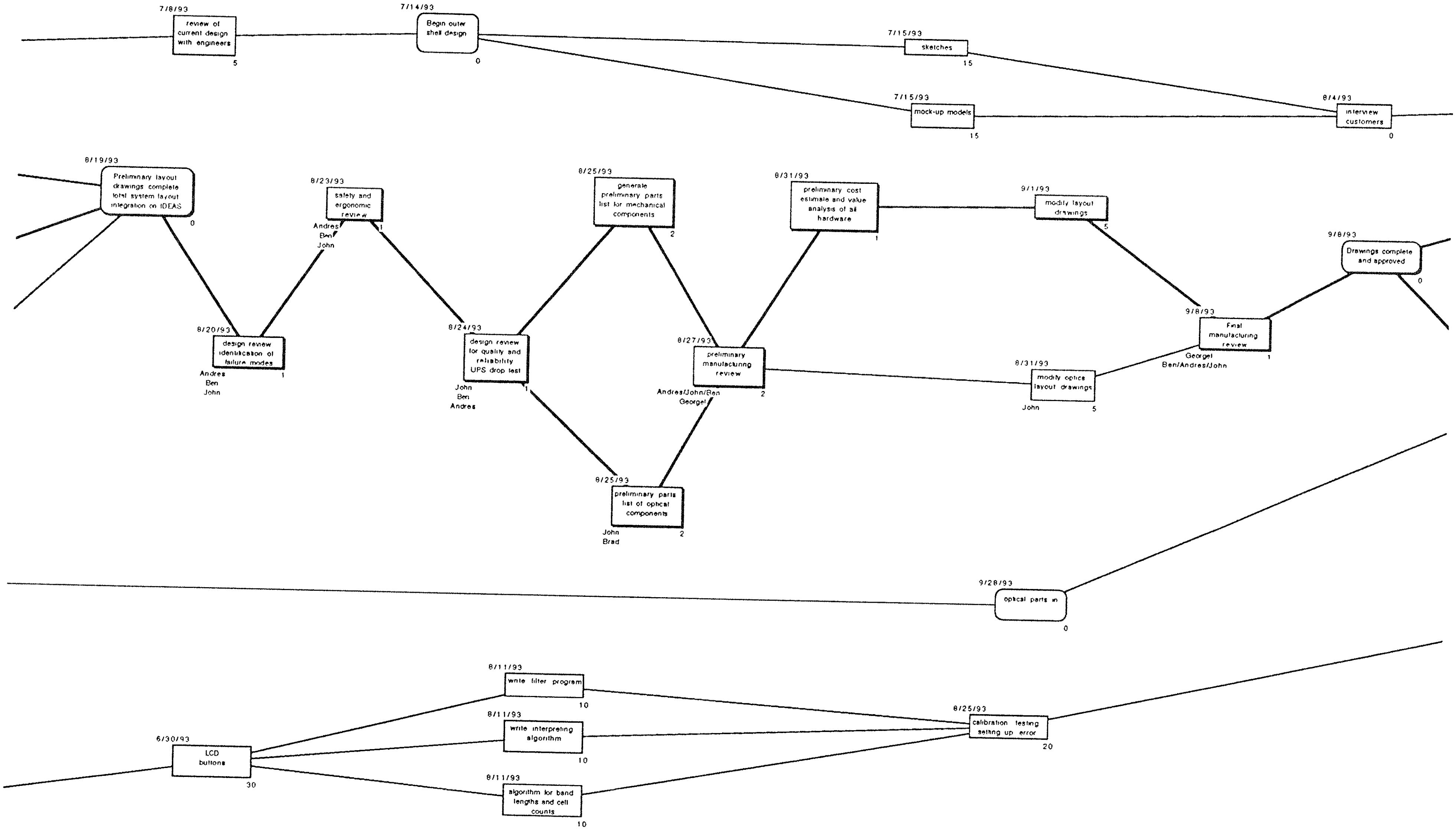
The production phase includes building the prototype, debugging and verifying its performance. The hardware for the prototype is generated from the detailed drawings from the design phase. However, some of the manufacturing processes to be used for production cannot be used in the alpha prototype due to the expense of tooling costs. Every attempt should be made to imitate the final product. For example, injection molded parts should have draft angles for the prototype. The material for the prototype should be the same or similar to the one used in the final product. When the parts return from the machine shop, assembly of the prototype should be done as if it were done on the plant floor. This way, the PDT will be able to identify problems that arise with assembly. The time and tools necessary for the assembly can also be determined.

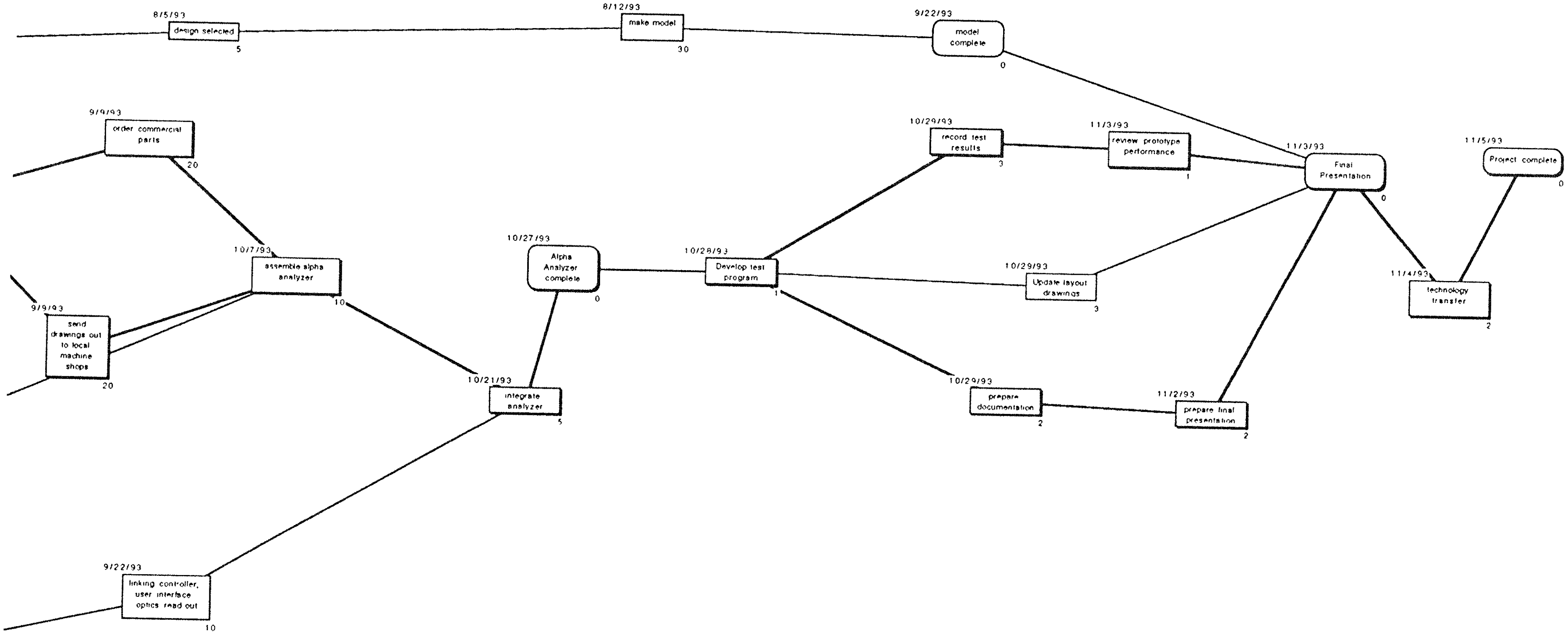
Invariably, there will be some problems with the prototype that need to be debugged. The problems might come from simple mistakes in the drawings or in the manufacturing of the parts. These parts might need some minor rework. Time must be allocated to fix these problems and be able to thoroughly test the prototype when it is complete. A first check is to test that the subsystems reach the same level of performance obtained during the parameter design. Then, the prototype is compared to the benchmark product to assure it has surpassed it. While doing these tests, the noises identified in the design phase should be added to the prototype to confirm its sensitivity. It is possible that some calibration be required to achieve maximum robustness of the total system.

The system verification is complete. The NPP alpha prototype is robust and it is better than any other competing product available in the market to date. When marketed, it will become the new benchmark for all competing products. The prototype is presented to the management of the sponsoring company who also agree that the product and the NPP is a success.



Appendix A- The Alpha Prototype CPM
MIT New Products Program
Becton-Dickinson Project


7/8/93
review of current design with engineers
5
7/14/93
Begin outer shell design
0
7/15/93
sketches
15
7/15/93
mock-up models
15
8/4/93
interview customers
0
8/19/93
Preliminary layout drawings complete total system layout integration on IDEAS
0
8/20/93
design review identification of failure modes
Andres
Ben
John
1
8/23/93
safety and ergonomic review
Andres
Ben
John
1
8/24/93
design review for quality and reliability UPS drop test
John
Ben
Andres
1
8/25/93
generate preliminary parts list for mechanical components
2
8/25/93
preliminary parts list of optical components
John
Brad
2
8/27/93
preliminary manufacturing review
Andres/John/Ben
George
2
8/31/93
preliminary cost estimate and value analysis of all hardware
1
9/1/93
modify layout drawings
5
8/31/93
modify optics layout drawings
John
5
9/8/93
Final manufacturing review
George
Ben/Andres/John
1
9/8/93
Drawings complete and approved
0
9/28/93
optical parts in
0
6/30/93
LCD buttons
30
8/11/93
write filter program
10
8/11/93
write interpreting algorithm
10
8/11/93
algorithm for band lengths and cell counts
10
8/25/93
calibration testing setting up error
20


8/5/93
design selected
5
8/12/93
make model
30
9/22/93
model complete
0
9/9/93
order commercial parts
20
10/7/93
assemble alpha analyzer
10
9/9/93
send drawings out to local machine shops
20
10/27/93
Alpha Analyzer complete
0
10/21/93
integrate analyzer
5
9/22/93
linking controller, user interface optics read out
10
10/28/93
Develop test program
1
10/29/93
record test results
3
11/3/93
review prototype performance
1
10/29/93
Update layout drawings
3
10/29/93
prepare documentation
2
11/2/93
prepare final presentation
2
11/3/93
Final Presentation
0
11/4/93
technology transfer
2
11/5/93
Project complete
0

Appendix B- QBC Walkaway System Design Specifications

Revised, August 11, 1993
Prepared By: Shin John Choi

I. Functional Specifications

A. Automated hematology instrument for CBC's, blood chemistry, and immunochemistry testing.

B. Tests made on disposable proprietary tube and float systems; both 111mL capillary tubes (EZ-Prep) and 500 mL Vac-Q-Tubes.

C. Bar code flag and label for ID.

D. Carousel loaded, fully automated spin/read system. User operations limited to loading carousel, pressing start button, and unloading tubes at end of cycle. No manual tube handling between load and unload.

E. Read all existing bands, report currently available QBC parameters, and print Hematology Diagnostic Reminders for each specimen.

F. 8 readings taken around tube to average out waviness of band.

G. QC testing. Ability to track QC results.

H. Accommodate future tests. (read additional bands/ integrated fluorescence)

I. Parallel printer port, RS-232 serial port, 3.5" floppy drive, hard drive, run by 80486 CPU.

II. Overall Requirements

A. Target cost:
$6,250. @ 1,000 units/ year. (sell for $15,000-$20,000)
$5,000 parts; $1250 labor and overhead.

B. Processing Time (maximum):
1 tube in 5.5 min; 10 tubes in 7 min.

C. Carousel Capacity:
10 tubes

D. Life Expectancy:
1. > 100,000 QBC's
2. Max. expected usage of 100 tubes/day.
3. Min. mean time before requiring service is 12 mo.; 18 mo. is desired.
4. 1,000 hrs. min. motor life.
5. Non-user replaceable lamps must last at least 50,000 QBC's.

E. Environmental Requirements:

1. Must operate between 20-32° C, 10-95% non-condensing humidity.
2. Store between -20 and 60°C.
3. Specimen temperature must not change >8° C, never exceed 37°C.
4. Must operate in ambient light from 10-150 ft. candles.
5. Operate with 2° surface incline in any direction with max. rotor imbalance.

F. Sound Level:

<65 dB

G. Size / Weight / Strength:

1. Largest 20"W x 26"D x 18" H (minimize footprint)
2. <30lbs gross weight
3. Must survive NSTA shipping test in its shipping container. (vibration and drop tests)

H. Centrifugation Force:

14,387 x g nominal for 5 min. spin cycle. 15 sec accel. and decel.
Stay between 14, 315 x g -14,458 x g.

I. Optical Requirements (approx 1.5:1, 50mm focal length)

1. Min. lens resolution of 20 line pairs/mm. w/ efficiency f/2 or better.
2. Grating (filter) must provide bandwidth of 20nm over the width of the pixel in the CCD.
3. CCD of at least 5,000 pixels to meet desired resolution.

III. Accuracy/ Precision

A. Must read band lengths down to 0.002" ± 0.0005"

B. Must be capable of measuring mechanical expansion factor of the individual float and glass tube, and use data to compensate.

C. Precision (Within Tube / Tube-to-Tube):

Parameter	**Within Tube**	**Tube-to-Tube**
Hematocrit	0.2%	2.0%
Hemoglobin	0.5%	2.0%
Total WBC	3.0%	8.0%
Lymph/Mono	5.0%	8.0%
Granulocytes	3.0%	5.0%
Platelets	5.0%	10.0%

Within tube precision is coefficient of variation of 10 readings on same tube on the same instrument when removed and reinserted between readings.
Tube-to-Tube precision is coefficient of variation of 10 tubes of the same blood sample read on the same instrument.

D. Accuracy (correlation with readings on existing impedance-type counter):

Parameter	**R**	**Mean Bias**
Platelets	>0.90	<5%
# Granulocytes	>0.90	<3%
# Lymphs/Monos	>0.85	<5%
Hematocrit	>0.90	<3%
Hemoglobin	>0.90	<3%

IV. Safety

A. No part of rotor or instrument can move outside of 30 cm safety zone surrounding instrument as a result of rotor failure. All fragments/ etc must be contained in the shield.

B. Carousel must be sealed inside rotor. Aerosol formation/ transport should be prevented.

C. Must meet established safety standards such as UL-1262, IEC-601, and IEC-1010.

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