Utilizing Quality Function Deployment (QFD) in the Development of a Next Generation Hematology Analyzer

by

Don J. Lee

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ABSTRACT

Quality Function Deployment is being used at MIT to develop a next generation hematology analyzer, the QBC® Walkaway, for Becton Dickinson (BD), a major US medical equipment corporation. The walkaway system, which automatically performs the necessary functions for blood analysis, consists of a centrifuge and a blood tube optical measurement station. An MIT product development team consisting of undergraduate and graduate students in mechanical and electrical engineering and management is working concurrently with BD to develop, from conception to prototype, an automated hematology analyzer. The target market segment is medium-sized physician practices (3-10 physicians) which was selected by BD, and the MIT team conducted the necessary market research to define customer requirements and to fully understand the competitors' products. Market research consisted of experiential interviews, a focus group, and card-sort interviews. These customer requirements were used to generate, evaluate, and select system concepts. The "House of Quality" method was used to translate customer requirements into engineering requirements.

The engineering team selected three systems for breadboarding and feasibility testing. Of the three systems, a QBC® blood tube imaging system using a CCD (charged-coupled device), the "CCD Imager" was chosen for continued development based on superior performance and cost-effectiveness. With this system, the team was able to reduce optical blood analysis time from the current machine capability of 2 minutes to a projected time of less than 15 seconds per blood sample. The team selected a patient identification system consisting of a pre-bar-coded blood tube and a correlated analysis results form which will minimize user error. A precision fluorescence method to measure tube and float tolerances, which has been developed by the inventors of the QBC® technology, will be incorporated to obtain high accuracy in optical band length measurement. A system has been defined and a prototype is currently being developed to meet BD corporate requirements for performance and future assays, government regulations for clinical medical diagnostic equipment, and customer requirements from the two target market segments.

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I would like to show my deepest appreciation to my team members who have given me tremendous amount of support, enthusiasm, and most importantly, friendship. Amy Battles, Benjamin Linder, Richard Wong, Karon MacLean, Mark Driscoll, Laura Edwards, Babu Anisetti, and Ming Wu ... thanks for everything for making my graduate years at MIT enjoyable and an extraordinary learning experience. I would like to give my special thanks to Laura Edwards for her help and criticisms with my thesis.

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PREFACE

Our product development team for Becton Dickinson's QBC® Walkaway project consists of a core group of graduate students, several contributing graduate and undergraduate students, and three faculty members from the three disciplines of mechanical engineering, electrical engineering, and management. The core group of engineering graduate students consists of mechanical engineering graduate students Amy Battles and myself; one graduate marketing student Babu Anisetti (who replaced Rich Wong after he graduated), and one electrical engineering graduate student Laura Edwards. Benjamin Linder, a graduate student in mechanical engineering, has observed and participated tremendously in engineering and marketing decisions with our team. Karon MacLean, a doctoral student in mechanical engineering, has been primarily responsible for the human interface aspects of the machine. Mark Driscoll, who recently received his Bachelor's degree in mechanical engineering, and more recently, undergraduates Sarinda Newell and Nanette Palmer, have contributed to this effort. Bachelor of Science candidate Ming Wu has made considerable contributions in a breadboard and optical system design. Andres Pieczanski, a graduate student in the mechanical engineering department, is a new core team member who took over my position. The team has been led by Michael Rosen, Ph.D., Principal Research Scientist in the Mechanical Engineering Department; David Otten, Principal Research Engineer in the Electrical Engineering Department; and William Qualls, Ph.D., Associate Professor of Marketing in the Sloan School of Management.

The product development team has worked closely in all aspects of engineering and marketing research; therefore the content of our Master's theses which have emerged from the project can be expected to be objectively similar but subjectively different. I will reference two other theses that have already emerged from the project: Richard Wong's Master's thesis for the Sloan School of Management on the preliminary QBC®

Walkaway market research, and Mark Driscoll's Mechanical Engineering Bachelor's thesis on the human interface element of the QBC® machine.

Acronyms

ACT/T	Average Cycle Time per Tube
BD	Becton Dickinson
CBC	Complete Blood Count
CCD	Charge-Coupled Device
CLIA-88	Clinical Laboratory Improvement Act of 1988
FDA	Federal Food and Drug Administration
FMEA	Failure Modes and Effects Analysis
HB	Hemoglobin
HCT	Hematocrit
HIV	Human Immune Deficiency Virus
HMO	Health Maintenance Organization
HoQ	House of Quality
LCD	Liquid Crystal Display
Lymph/mono	Lymphocyte/Monocyte
MIT	Massachusetts Institute of Technology
NPP	New Products Program
PDT	Product Development Team
PLT	Platelets
QBC®	Quantitative Buffy Count
QFD	Quality Function Deployment
RBC	Red Blood Cells
UL	Underwriter's Laboratory
WBC	White Blood Cells

1. Introduction

The immense global competition from powerful and ever-threatening economic nations from Asia and Europe drives US corporations to find and use more effective methods to develop new products faster, better, and more economically. Many major US corporations, such as Ford Motor Company, Xerox Corporation, Chrysler, General Motors, IBM, and Motorola, have adopted product development and manufacturing methodologies that have helped them to sharpen their competitive edge.[1,2,3,4] These methodologies are often referred to as *Quality Function Deployment* (QFD). QFD was developed in 1972 at Mitsubishi's Kobe shipyard to integrate marketing and engineering.[5] It was introduced into the US by Ford Motor Company and Xerox Corporation in 1986. A multi-functional product development team (PDT) that includes marketing, engineering, and manufacturing works in parallel on developing a product that satisfies customer needs. Many companies have adopted or are adopting these methods. Unfortunately, many US corporations are still in a rudimentary stage in implementing these vital product development techniques.[6]

1.1 MIT New Products Program

The Mechanical Engineering Department at the Massachusetts Institute of Technology has recognized the need for educating students in product development methodologies to maintain the global economic leadership of the US. Professor Woodie Flowers and colleagues in the Mechanical Engineering Department and other departments of MIT established the New Products Program (NPP) to meet the concerns of the US corporations by providing them with leaders in engineering. In this program, graduate students from the various engineering disciplines and from the Sloan School of Management are selected to form a team that will develop a new product sponsored by a major corporation from concept to a final production prototype. The team members, usually faculty and graduate students from mechanical engineering, electrical engineering, and marketing, work very closely *in parallel*, getting involved concurrently in many phases of product development.

Becton Dickinson (BD) is a major US corporation specializing in medical instruments which is interested in trying to adopt the new product development techiques. In the fall of 1991, BD's Primary Care Diagnostics Division made a decision to sponsor an NPP team to develop the next generation of "Quantitative Buffy Count" (QBC®) machines: QBC® Walkaway. This machine will be used for hematology analyses in medical laboratories and larger doctor's offices to provide complete blood cell counts and probable diagnoses of patients. The blood cell counts can provide information relevant to diagnosis of a variety of diseases. The term "walkaway" implies that the user just needs to insert blood samples into the machine, *walk away*, and return later to get the printed blood count results and diagnostic reminders. Ultimately, there are three goals that BD would like to achieve from the development of this machine: 1) to study QFD and learn its effectiveness; 2) to develop the first generation of fully automatic hematology instruments; and 3) to implement QFD and concurrent engineering techniques for future products.

The goal of the MIT/BD product development team is to develop a machine that incorporates a centrifuge, a reader, and a user interface in one unit which can perform blood analyses and present results automatically without the need for any human intervention or contact with blood, with the exception for phlebotomy (drawing the blood from the patient) and inserting blood samples into the machine. In the process of developing this machine, the team is developing innovative methods to measure blood parameters, incorporating new machine features, and user-friendly human interface.

My thesis focuses on the QFD methods and activities in developing the Walkaway QBC. QFD methods used by the team include conceptual brainstorming activities, the Pugh concept selection process, failure mode and effects analyses, customer interviews, and the House of Quality. I will discuss the rationale behind the many important decisions in both engineering and marketing and some new methods different from those currently taught, that were introduced by the team to help make the product development process more effective. Furthermore, since teamwork is extremely important to the success of concurrent engineering, I have presented throughout this thesis, the incredible and unique group dynamics that I have experienced with my team.

1.2 Introduction to Hematology

Hematology (as defined by the American Heritage Dictionary) is the study of generation, anatomy, physiology, pathology, and therapeutics of blood. Blood is a tissue (substrate) consisting of red blood cells (RBC) also known as erythrocytes; white blood cells (WBC) also known as leucocytes; and other blood cells. RBCs are red and orange in appearance. The main component of RBC is hemoglobin, which is responsible for transporting oxygen throughout the body. WBCs are categorized into two sub-groups known as granulocytes and non-granulocytes, both of which are components of the immune system (Figure 1.1). Another component of blood, the thrombocytes, create the platelets needed to stop bleeding and maintain the mechanical integrity of the vascular system.

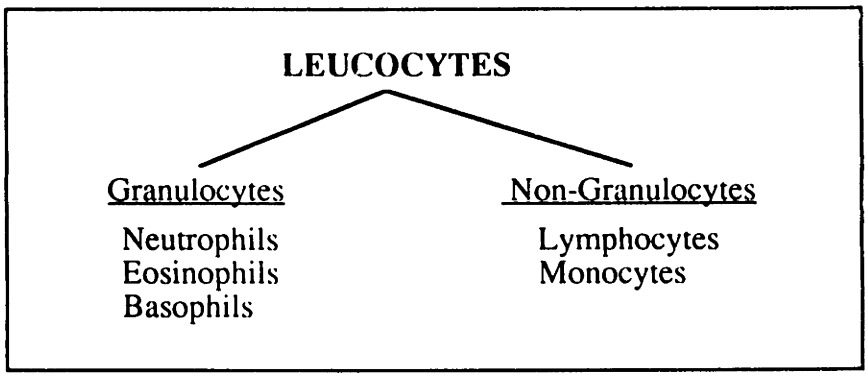


Figure 1.1 Breakdown of Leucocytes

Granulocytes are composed of neutrophils, eosinophils, and basophils, while non-granulocytes include lymphocytes and monocytes. Neutrophils, the most common element of the granulocytes, defend against pyogenic infections. Eosinophils defend against parasites and also cause hypersensitive reaction (allergy). Basophils contain histamine and heparin which also lead to hypersensitive reaction. The lymphocytes produce anti-bodies for body's immune response defense and include two types: T-lymphocytes and B-lymphocytes.

Blood Sedimentation

After blood has been aspirated into a test tube, two layers are formed consisting of a coagulated "jelly-like" mass at the bottom of the tube and a serum at the top. Using an anti-coagulant prevents this jelly-like mass from forming and keeps the blood components separated. After centrifuging the test tube with the anti-coagulant, the blood separates (from top to bottom) into plasma, buffy coat, and RBC. The buffy coat is layered with non-granulocytes at the top and granulocytes at the bottom. The current generation of QBC® determines the concentrations and cell counts of the white blood cells in this buffy coat as well as various red cell parameters and platelet counts.

1.3 History and Future of QBC Technology

Physicians are often in need of immediate hematological results to properly diagnose patients in a timely manner. Not too long ago, physicians typically had three tasks: perform a laborious "manual blood cell count," send the patient to an emergency room for a rapid blood test, or send out a blood sample to an external laboratory and wait up to a day to get a complete blood count (CBC)[7]. In manual blood cell counts, blood smears with different staining techniques allow the microscopic identification of different types of blood cells and platelets. A differential count as well as a cell quality examination can be performed with this method.

However, a larger practice has the option of hiring a medical technician to run a rather complex electronic cell counting hematology analyzer. The machines using this technology are manufactured by various companies such as Coulter, Baker, & Unipath to count and provide the morphology of white and red blood cells by using electrical resistance feedback across a small aperture where indivdual cells pass through. These machines often require a lot of operator training and maintenance, and can cost up to $250,000. They can detect abnormal blood cells but cannot identify them, so that a manual inspection is still necessary when abnormalities are detected.

In 1976, Robert A. Levine and Stephen C. Wardlaw developed a simple technique to count blood cells with the rather ancient approach of observing blood cell layers after settling. This blood analysis technique involves determining the heights of blood cell layers in a capillary tube after centrifugation, which increases the rate of cell sedimentation.[8] The layers that are formed from top to bottom are plasma, platelets, white blood cells (non-granulocytes and granulocytes), and red blood cells. However, the white blood cell layer height, also known as the *buffy coat,* is quite miniscule compared to the red blood cell layer height. To perform a quantitative buffy coat measurement, the Levine and Wardlaw approach uses a precise cylindrical plastic float which has density less than that of red blood cells. The float is inserted into a precise cylindrical capillary tube.

After centrifugation, the thin buffy coat layer has expanded in the annulus between the float and the capillary tube (Figure 1.2). An expansion factor of approximately 10 was determined to be optimal based on float and capillary tube tolerances and the measuring accuracy of low cell counts of the buffy coat. This expansion in the annulus would allow the white blood cell layers to be measured easily with a higher degree of precision.

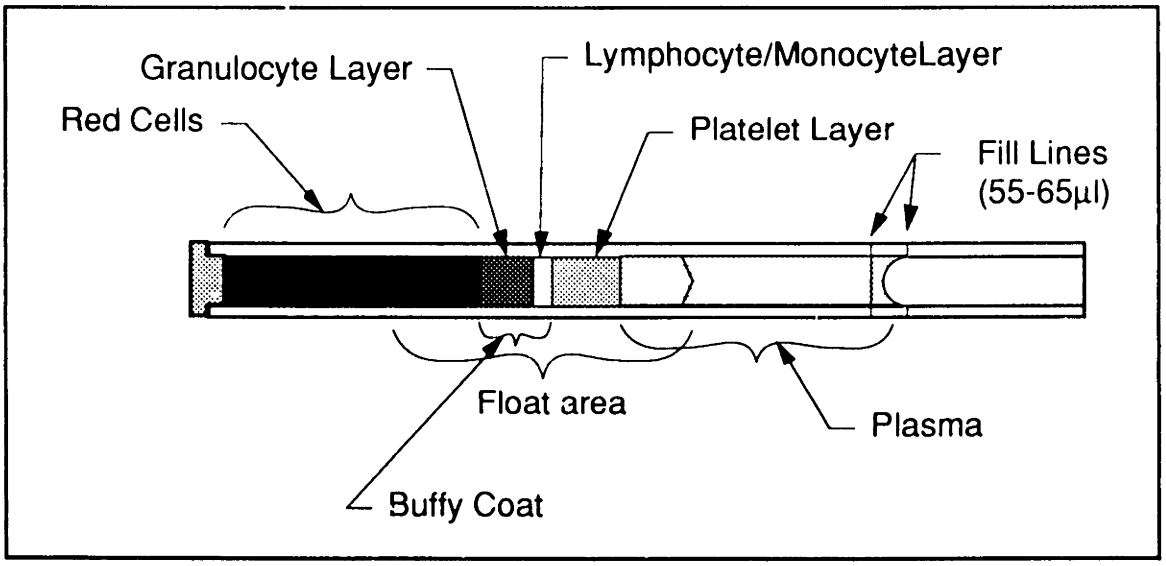


Figure 1.2 Centrifuged capillary blood tube

To make the components of the buffy coat layer more visible, acridine orange is used as a fluorescence reagent. The acridine orange is absorbed by the white blood cells causing the granulocytes to fluoresce yellow and the non-granulocytes to fluoresce bright green. The platelets fluoresce orange and the plasma fluoresces green. With these distinct boundaries, the heights of the buffy coat components are easily measured. Knowing the cell counts beforehand, a linear relationship between the cell layer heights and count is developed.

Levine and Wardlaw found a couple of problems with blurring of the boundary between the red blood cells and the granulocytes. In some samples of blood, the layers of red blood cells and the granulocytes sometimes overlapped. In order to obtain a more distinct boundary between

the red blood cells and the granulocytes, potassium oxalate was later added. This reagent shrunk the size of the red blood cells and hence made them denser allowing a more distinct boundary between the red cells and granulocytes. However, patients with red-cell fragmentation syndromes often had more red blood cell membranes which were less dense than the internal red cell contents. The potassium oxalate seemingly was not effective with these cells so an agglutinating reagent was added to allow the low density red blood cells to combine with the higher density ones. This reagent, a glycophorin-specific monoclonal antibody, produced a red cell layer that had a constant density over the entire height of the layer rather than a continuously varying red cell density layer associated with the higher density cells at the bottom and the lower density cells at the top.

This technique of blood analysis was marketed by Becton Dickinson as QBC® in 1983 after Federal Food and Drug Adminstration's approval. The centrifugation and reading of a capillary tube only requires approximately 7 minutes. Unlike the electronic cell counting method, the QBC® system requires no handling of reagents because all the necessary reagents are coated inside the capillary tubes. This product is ideal for small physician practices that require inexpensive and nearly instant blood analyses. A variation of the QBC® was also developed to perform quantitative buffy coat analysis for parasite detection in animals. Another modified version was developed to diagnose parasitic diseases in human patients in underdeveloped countries.

There is potential for the QBC® machines to analyze additional blood parameters such as numbers of reticulocytes, glyco-hemoglobin, and CD4 cells (for HIV detection). Fluorescence reagents and new measuring techniques are in the process of being developed to detect and quantify new parameters. Currently, there is a variety of QBC® machines marketed by Becton Dickinson. The *QBC® Autoreader* can automatically analyze various blood parameters and provide any diagnosis associated with a blood sample. Just this year, a new technique using lasers has been developed to measure bands to quickly provide a limited number of blood parameters in a hand-sized unit called *Hemascan*.

1.4 Current QBC® Technology and Products

The most recent QBC® system in the market is the "QBC® Autoreader" and the "World-Class Centrifuge" which cost around $13,000 and $3000 respectively. This system is sold to small physician offices and other small practices. The system can provide the following hematology parameters from a centrifuged capillary tube:

- Hematocrit (HCT)
- Hemoglobin (HB)
- Platelet Count (PLT)
- White Blood Cell Count (WBC)
- Granulocyte Count (% and number)
- Non-Granulocyte (Lymphocyte/Monocyte) count (% and number)
- Fibrinogen (a dedicated capillary tube and an optional QBC® Incubator is needed)

The system can handle 3 basic types of capillary blood tubes: capillary, venous, and fibrinogen blood tubes (see Appendix A for more details). Each of the tubes have different pre-centrifuge procedures:

The *capillary* tube is filled with 55 to 65 µl of blood through capillary action from a finger puncture. Blood needs to be filled from the proper end of the tube so that anti-coagulating agents will take effect. A float is inserted and then a closure (cap) is manually seated at the correct end of the tube.

The *venous and fibrinogen capillary* tubes are obtained through a more complex procedure. Blood is drawn from a vein using a Vacu-Tainer® blood collection tube. The Vacu-tainer® cap is removed and a venous capillary tube is inserted and properly filled using a calibrated hand-actuated pipettor. A float is inserted into the venous capillary tube and a closure is manually seated at the proper end of the tube.

Becton Dickinson will be introducing two new blood tubes, EZ-Prep® and Vacu-Tubes®, that are pre-inserted with floats and reagents and pre-capped with closures. The EZ-Prep tube will replace the capillary tube and eliminate the need for manual float insertion and manual closure capping. The Vacu-Tube® will replace the venous capillary tube. It is a completely vacuum-sealed system that contains the necessary reagents and a float. Venous blood is automatically drawn into the Vacu-Tube® by the vacuum through a needle directly from the patient. After phlebotomy, no other procedure need to be followed before centrifuging. The Vacu-Tube will eliminate any unnecessary exposure to blood with the exception for phlebotomy.

After blood tubes are properly filled, they are centrifuged in the World-Class Centrifuge for 5 minutes. A centrifuge is capable of accommodating a maximum of 20 tubes for batch jobs. The tube positions in the numbered slots of the centrifuge rotor must be recorded manually for patient identification. The QBC® Autoreader must be calibrated at the start of each day with a calibration capillary tube. The calibration procedure takes about 2 minutes. After centrifugation, one tube at a time is inserted into the QBC® Autoreader for automatic hematology analysis. The Autoreader can only analyze one tube at a time. The analysis cycle-time per tube is approximately 2 minutes. So the minimum possible average cycle time per tube (ACT/T) is about 135 seconds when batched with 20 tubes in the centrifuge as described in the following calculations.

centrifuge time :	5 minutes
analysis time for 20 tubes:	2 min./tube x 20 tubes = 2 minutes x 20 = 40 minutes
total time for 20 tubes:	45 minutes
ACT/T:	**(45 minutes x 60) / 20 tubes = 135 seconds**

The ACT/T for fibrinogen tubes would take a little longer since they need to be incubated before analysis.

The Autoreader automatically performs the necessary tasks to obtain the hematology parameters after the machine's cover is closed (Appendix

A). A handling mechanism grabs the tube and moves it axially to the optical reading station. An initial rough scan along the axis of the tube locates the fill line, meniscus, float area, and closure. After this scan, three more detailed axial scans, two fluorescence readings and one transmission reading, are performed.

For fluorescence readings, a lamp with a blue excitation light turns on (Figure 1.3). The excitation light is focused on the tube 90 to 135 degrees from where the optical sensor is focused. During a tube scan, the fluorescence light emitted from the blood tube is transmitted through one of the two color filters to the optical sensor for either green or red fluorescence reading. The optical sensor detects fluorescence intensity at each small axial increment along the tube as the tube is axially moved.

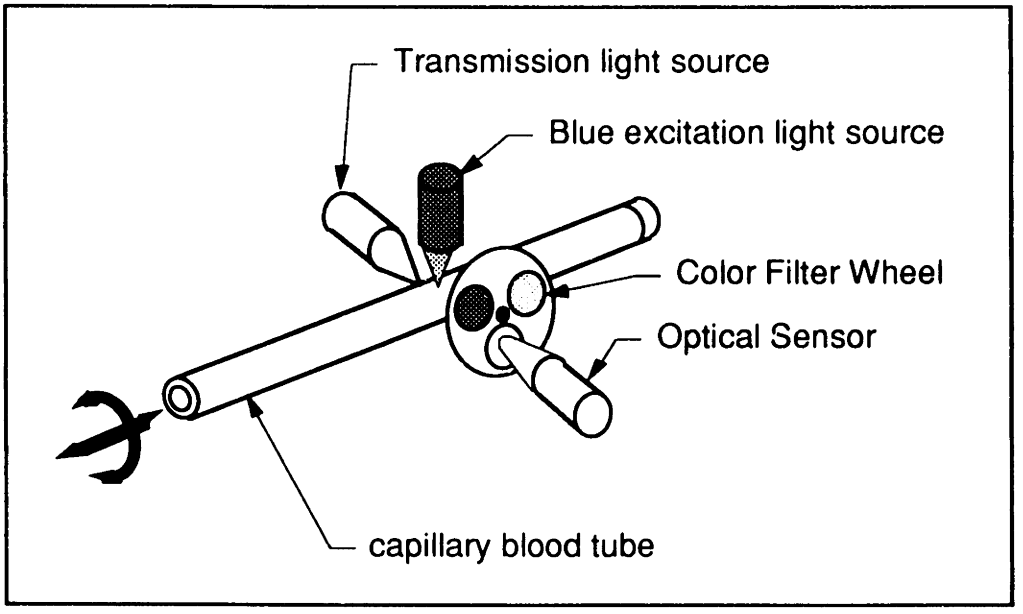


Figure 1.3 QBC® Autoreader Optical Reading Mechanism

During the transmission reading, a white light source is focused on the blood tube, the blue excitation light is turned off, and the color filter is removed from the front of the optical sensor. The transmission intensity through the diameter of the tube is detected and measured by the same optical sensor for each axial increment of the tube.

The three optical scans described above are performed eight times around the circumference of the tube. The eight sets of fluorescence and transmission readings that encompass the blood component bandlengths are averaged for the final hematology results to avoid error resulting from wavy band layers. These hematology results and corresponding diagnostic reminders are printed out on a standard computer printer directly connected to the Autoreader (see Appendix A).

1.5 MIT Team's Concurrent Engineering Process

The MIT team's concurrent engineering activities incorporate engineering, market research, and human interface. A core-team member has participated in almost every aspect of the QBC® Walkaway system's development (Figure 1.4). Engineering and marketing expertise have been continually exchanged to let all team members (core and peripheral) understand each other's position and background. This level of understanding has promoted constructive communication and decision-making at team meetings. Undergraduate and graduate research students usually worked on mini-projects with the core-team, such as performing feasibility experiments and examining design theories related to the project.

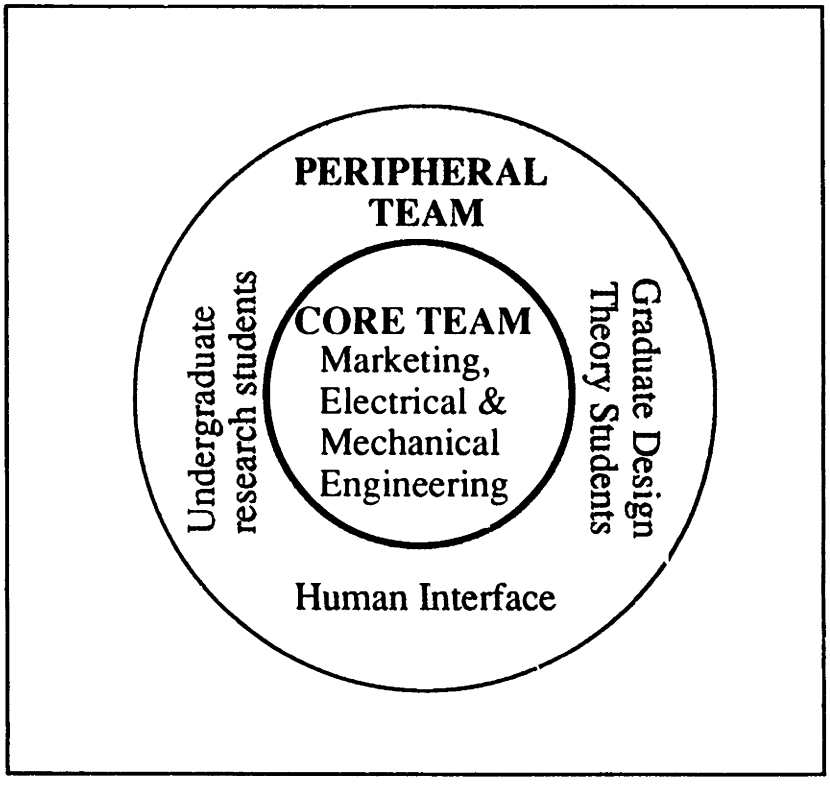


Figure 1.4 MIT Team Layout

Human interface also has been continually updated. As the QBC® Walkaway system gradually became more concrete, the human interface aspects were evaluated and then simulated. These simulations have been used to get customer feedback. At the same time, marketing members have continued to gradually develop a greater understanding for customer needs. Team effort has been very dynamic and the concurrent engineering kept everyone in touch with the progress of the QBC® Walkaway system. This simultaneous process has allowed each team member to raise any design issues immediately to expedite problem solving. Our team's simultaneous process is outlined in figure 1.5 and the project timetable is found in Appendix B. In this thesis, I will describe only the activities up to the prototype development stage.

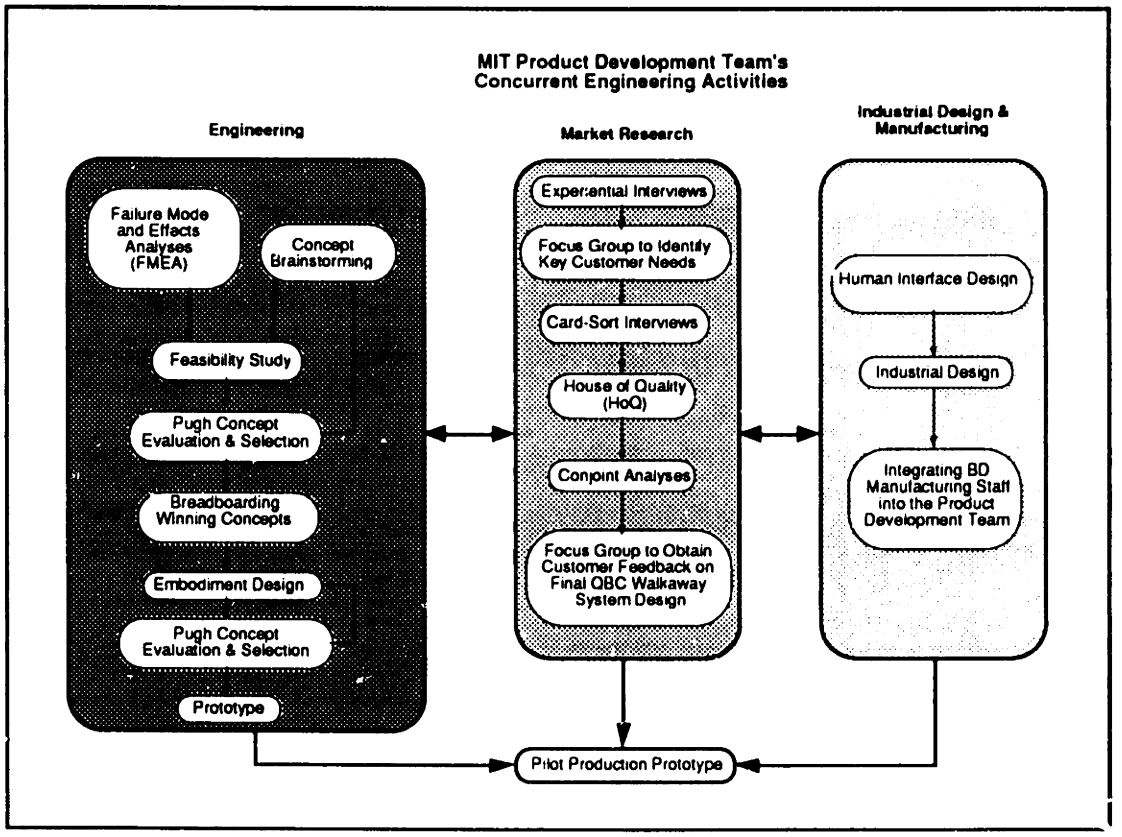


Figure 1.5 Concurrent Engineering Process

At the start of the project, our engineers and marketing graduate students conducted research on current hematology machines. After understanding the QBC® and competing technologies, the team conducted "experiential interviews" to obtain preliminary customer feedback on current hematology analyzers (Section 2.2). We gradually accumulated data on customer needs and generated a list of design requirements to begin brainstorming ideas for the QBC® Walkaway system (Section 2.4). As we gathered more customer information, we gained a higher level of understanding of customer needs for hematology analyzers.

Many product development activities have been occurring simultaneously since QBC® Walkaway's conception. The human interface aspects were considered from the beginning so that the exterior system design could be generated in parallel to engineering and marketing demands. Customer requirements and their relative importance acquired from experiential interviews, focus group sessions, and card-sort interviews were used to develop the House of Quality (HoQ) (Chapter 2). We used HoQ to translate customer requirements to engineering requirements, understand customer views on current hematology analyzers, develop a relationship between customer and engineering attributes, and finally, generate a goal for each of the engineering design requirements. We used the Pugh concept selection process to generate, evaluate and select feasible concepts (Chapter 3). We used this process throughout the course of the project to fulfill customer and corporate requirements.

When strong concepts emerged, we developed three breadboards to determine their feasibility (Chapter 4). As this engineering activity was happening, human interface issues were considered and external system configurations gradually were maturing. Customer interviews were conducted with various human interface simulations in areas such as computer display, menu options, and method of information input and output.[9] Marketing members also conducted surveys and more interviews to perform conjoint analysis to understand how potential customers would trade-off between cost and system features.

As system configurations changed when market information was updated, our engineering team members were ready to adapt to the changes.

However, since changes required more engineering time, effort and resources, careful decisions had to be made to accommodate tight schedules. The human interface simulations were setup to adapt to new developments using the software package Supercard™for the Apple Macintosh computer systems. Daily electronic-mail communication between team members and Becton Dickinson kept everyone updated on the product's development. Understanding that system requirements were gradually being developed, we generated system concepts by attempting to anticipate conceivable customer expectations based on our experience from interviews and focus group. This foresight allowed us to switch concepts with less effort because we were already familiar with many concept options.

At this writing, the final system has been defined for prototype development. We are currently in the embodiment design phase for an alpha prototype. We have just brought in a BD manufacturing manager to the team to supply feedback on manufacturing issues before building the prototype.

Our concurrent engineering activities have been dynamic with frequent cross-functional communication with supervisors and core team members. This communication process was effective with the product development cycles.

2. Voice of the Customer

This chapter describes the engineer's viewpoint of the market research conducted for the QBC® Walkaway system which include market segment definition, customer interviews, competitor analyses, and focus groups. I will give a comprehensive discussion on how market research was used in engineering and my experiences with market research during the system's development. The market research was guided mainly by the marketing graduate students Richard Wong and Babu Anisetti and by Professor William Qualls. Aspects of the market research which dealt with obtaining customer feedback were often conducted with the help of the core team members. The marketing students performed the necessary analyses to establish the relative importance of customer needs (for the "House of Quality") and also analyzed customer trade-offs between cost and features (conjoint analyses). Richard Wong outlines the method of acquiring and determining key customer needs in his Master's thesis.[10] Babu Anisetti's Master's thesis will detail the methods and results of the conjoint analyses. The market research process, in which the entire team has participated, is as follows:

1. Preliminary *Experiential Interviews* identified customer needs.

2. A *Focus Group* identified more needs and wishes through a formal session with potential customers.

3. *Card-Sort Interviews* determined the relative importance of the customer needs which were established through the focus group and experiential interviews.

4. The *House of Quality*[11] integrated all of the market research data on customer needs and translated it into engineering design attributes.

5. *Conjoint Analyses* were helpful for understanding customer trade-offs between product features and price.

2.1 Target Market and Competitors

2.1.1 Hematology Analysis Methods

There are currently four methods of counting blood cells:

1. *Manual* -- stained blood cells are counted under a microscope
2. *Impedance-counting* -- blood cells are counted and differentiated by determining their individual electrical resistances as they flow through an orifice
3. *Light Scattering and Flow Cytometry Devices* -- laser excites blood cells and their fluorescence is measured to count individual blood cells
4. *Centrifugation and Blood Band Reading* -- blood cell counts are determined by the length of bands in a centrifuged blood tube (current QBC® technology)

The most common hematology analysis method used in large physician practices, hospitals, and clinical laboratories is impedance-counting. Manual cell counting is nearly obsolete. However, blood smears are often analyzed under a microscope by medical technicians when abnormalities are detected through an impedance-counting method. This method cannot identify abnormal cells. Laser scattering devices are also used to count cells and determine cell morphology; Sysmex R-1000 machine, manufactured by TOA Medical Electronics Company, uses flow cytometry and laser scattering for automated reticulocyte analyses. The QBC® technology is well-known to small physician practices (1 or 2 physicians) but it is practically unknown in larger practices (over 3 physicians) and clinical laboratories. BD intends to move the QBC® Walkaway system into these larger practices and clinical labs.

2.1.2 The QBC® Walkaway System Market

The QBC® Walkaway system has been focused on medium-sized (3-10 physicians) physician practices and hospitals. In these market segments, the four most common specialties that perform hematology analyses are:

- General Practices / Family Practices
- Internal Medicine
- Pediatrics
- Obstetrics / Gynecology

The potential competitors to the QBC® Walkaway are machines manufactured by Coulter, Unipath, Sysmex, Danam, and Baker. The main competitor will probably be Coulter's impedance-counting system. The Coulter systems are used in many hospitals and group practices and are perceived to be the "gold standard" by many medical technicians.

QBC® Walkaway system will most likely be compared to low-end and high-end Coulter systems: Coulter T540 and STKR. These systems have the following specifications:

The QBC® Walkaway system, as specified by BD and customers (through market research), will include more value-added features than the Autoreader and can possibly be upgraded to measure many more blood parameters (Table 2.1). The QBC® Walkaway system will differ from the Autoreader system in the following ways:

- walkaway capability
- higher accuracy and precision
- higher throughput
- more blood parameter measurements
- lower capital cost and maintenance
- automatic patient identification
- automatic diagnostic reminders
- easier to use
- market target is medium-sized physician practices and possibly hospitals

Features	Coulter T540	Coulter STKR	QBC® Autoreader	QBC® Walkaway
walkaway capability	no	yes	no	yes
batch size	1 sample at a time	100 samples, maximum	1 sample for analysis and 20 samples for centrifuge	40 samples, maximum
automatic patient identification (correlates sample to patient)	no, patient identification is manually recorded	no, only automatic bar code reading that provides sample position in a batch	no, patient identification is manually recorded	yes
precision: • hematocrit • hemoglobin • RBC • WBC • lymph/mono • granulocytes • platelets	 N/A <1.5 % <2.0 % <2.0 % N/A N/A <4.0 %		 2.3 % 1.5 % N/A 8.3 % 14.9 % 7.4 % 11.7 %	 0.2 % 0.5 % N/A 3.0 % 5.0 % 3.0 % 5.0 %
differentiate types and sizes of blood cells detected	yes	yes	only type of blood cells	only type of blood cells
cycle time per sample	40 seconds	40 seconds	7 minutes for one sample *or* 2.5 minutes when centrifuged with a 20 sample batch	5.5 minutes for one sample *or* 30 seconds when centrifuged with a 20 sample batch
system cost	$18,000	$100,000	$16,000	$15,000-$20,000
annual service cost:	$3000	$15,000	$0	$0
disposable cost per sample	$0.90	$0.90	$2.50	$2.50
system requires a lot of maintenance	yes	yes	no	no
operator needs technical training to use the system	yes	yes	no	no
interfaceable to laboratory interface system	no	yes	no	yes
Other blood parameters			• fibrinogen	• reticulocyte counts • fibrinogen • CD4 counts • glyco-hemoglobin distribution
primary market	3 or more physician practices	10 or more physician practices	1 or 2 physician practices	3-10 physician practices

Table 2.1 Hematology analyzer comparison

These improvements may give QBC® technology a competitive advantage over Coulter's impedance-counting systems. QBC® Walkaway's lower cost, lower average cycle time per sample, lower maintenance, automatic patient identification, and ease of use might make it an attractive alternative for medium-sized physician practices to perform hematology analyses "in-house" rather than purchasing an expensive Coulter system or sending blood samples and/or patients to nearby clinical laboratories.

2.2 Experiential Interviews

Before our design team could conduct interviews, we had to familiarize ourselves with all the the current hematology analysis technologies: electrical blood cell counting, optical blood cell counting, and , of course, QBC®. We gathered information on the competitors as well as on the QBC® technology from Becton Dickinson. After gaining an understanding of the various hematology analyzers, we performed some preliminary experiential interviews to obtain some customer feedback.

Each of the four graduate students on the team at that time (Amy, Richard, Ben, and I) were assigned to one of the four market segments. We interviewed both medical technicians and laboratory supervisors. These interviews at customer sites gave us some insight about the customers' knowledge, work habits, work areas, and their hematology machines. We conducted experiential interviews with medical technicians and supervisors at a Health Management Organization (HMO), military hospital, hematology/oncology private practice, and several university medical centers. Richard Wong's thesis describes these interviews in detail[12].

There are many aspects of an interview which are difficult to record in words. For example, customers' subtle reactions, such as the level of disappointment conveyed by a grimace to a specific product feature may provide a unique experience for the product development team member. These intimate customer interactions might cause the team member to be particularly concerned with that product feature and to modify it in the final product to best satisfy the customer. It is therefore suggested to have engineering team members participate in customer interviews.

2.3 Focus Group

A focus group is a marketing tool that brings together potential customers and generates discussions to help to identify their needs for a specific product.[13,14] A focus group session may obtain feedback from customers about their experiences with current products and their expectations from future products. It is often led by an experienced moderator who effectively directs and stimulates the group with scenarios and questions to obtain the necessary information that will aid the design team to develop the most successful product.

The moderator of our focus group, Warren Cormier from the Boston Research Group, spent time with the design team before the focus group session to understand the goals of the team, the various hematology analysis technologies, and the current market. Our collected experiences and knowledge from the experiential interviews, as described in the previous section, helped to generate many questions and scenarios for the moderator to discuss with the focus group.

Our first focus group session was held with the goal of determining an initial set of customer attributes, testing many of our expectations about the specific features expected from a general hematology machine, and learning as much as possible about the competition. The experiences of the medical technicians in the target maket allowed the team to develop preliminary design guidelines and criteria as well as to initiate marketing strategy for the QBC® Walkaway system.

2.3.1 Focus Group Session Description

Our focus group session was held at FieldWorks in Waltham, Massachusetts in a room with a one-way glass window. The MIT design team was in an adjacent sound-proof observation room behind the one-way glass. Sound from the session room was conveyed through speakers in the

design team's room. The focus group was informed that the session was being recorded and observed by the team. Figure 2.1 shows the layout of the focus group members and the machines that they were using at the time of the session.

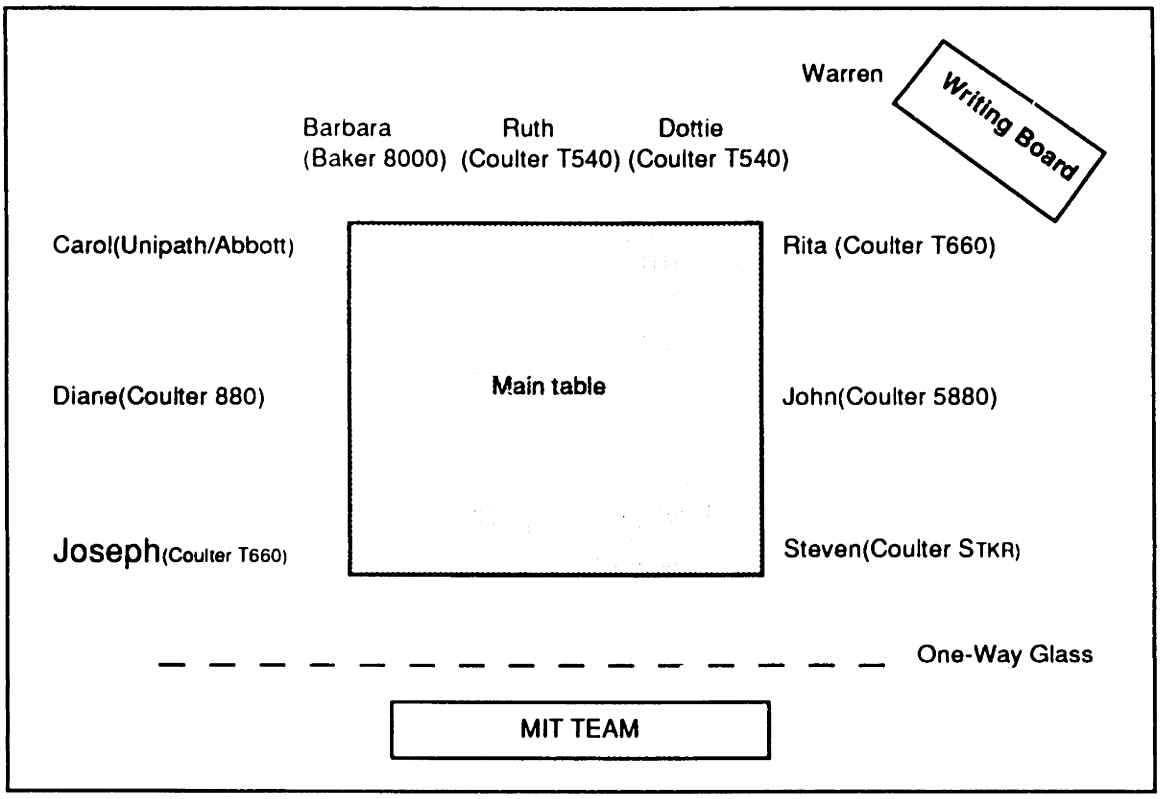


Figure 2.1 Focus Group Layout

All the medical technicians and supervisors were using impedance counters made by companies who manufacture impedance-counting hematology systems: Baker, Unipath, and most notably, Coulter. They were all unfamiliar with the QBC® technology; this was expected, since the QBC® machines are not sold in their market segments. Our experiential interviews also confirmed this fact.

During the session, Warren asked the group to become the designers of an ideal hematology machine. As a starting point, he suggested that they identify the key concerns and issues relating to blood analysis machines, as

well as the useful design features and desired areas for improvement in current machines. When this line of thought was exhausted, Warren referred to a list of categories(probes) which we had extrapolated from experiential interviews before the focus group; we wanted to be certain that most categories were covered (Table 2.1)

CUSTOMER CONCERN & NEED CATEGORIES
• Size
• Maintenance
• Speed
• Sample Handling
• Disadvantages of Patient I.D.
• Data Management
• Menu
• Disadvantages of Reagents
• Overall System

Table 2.2. Customer concern and need categories from focus group

The group was asked to consider each category and explain in detail the areas where the current machines can be improved. It was difficult for people who were not designers to think of ideas for improvement, let alone generate new ideas. There were only a few members who provided very constructive comments. One medical technician, John, was identified as a "lead consumer"; he was very comfortable and productive at this task. The others mainly confirmed each other's opinions or were silent. The moderator attempted to get input from all the members of the focus group session. The moderator's guide to establish customer needs and concerns along with the focus group results can be found in Appendix C. The outcome of this session is explained in the next section.

2.3.2 Focus Group Outcome

This section details the list of customer concerns and needs generated by the focus group (Table 2.1) based only on impedance-counting hematology machines.

Size

The medical technicians and laboratory supervisors in the group stressed that counterspace is limited and maintenance was difficult because of machine size and weight. They expressed a desire for a short and thin "breadbox-sized" machine.

Maintenance

A disadvantage to impedance-counting machines was the need for frequent, time-consuming and often complex daily and monthly maintenance. Due to the complexity of impedance-counting technology, medical technicians are trained directly by the manufacturer in machine operation and maintenance. There are many plastic tubings which need frequent maintenance in order to properly transport blood and reagents. The focus group suggested that a color coded tubing system with easy access and easy to read maintenance manuals would simplify maintenance and reduce the chances for contamination due to accidentally disconnecting or connecting a tubing.

Speed

An important issue was cycle time per analyzed sample. Doctors usually request patient hematology or any other chemical analyses to be performed as soon as possible. In addition, a medical technician time is precious so any feature which minimizes time was preferable. We observed

the hectic atmosphere of clinical laboratories during experiential interviews; medical technicians were usually quite busy performing many different tasks. Thus, any aspect of the machine that eliminates unnecessary effort and time is desirable. Such features include self-maintenance or no maintenance, automatic calibration, user-friendly instruction manuals with clear pictures, automatic patient identification, and, of course, high sample throughput.

Sample Handling

Reducing sample handling can help prevent the exposure to bloodborne pathogens and reduce the likelihood of making patient identification errors. For reasons of personal safety, the medical technicians preferred to minimize contact with blood samples. Opening blood samples would often expose them to blood aerosols which may be accidentally inhaled or come in contact with open wounds despite the many safety precautions that the medical technicians follow. Hence, automatic sample processing (*walkaway* capability) is a desirable feature to minimize blood sample handling .

Disadvantages of Patient Identification

The disadvantages of the current hematology machines that the focus group expressed were the small labels, the ink mark smears on the labels and the burdensome methods of matching samples to patients. Small self-adhering labels are quite awkward to handle and stick onto small blood tubes. The difficulty increases when the user is wearing protective latex gloves. Labels which use handwritten ink can smear during handling. In addition to the problems with current sample labeling methods, the medical technicians need to keep track of patient information manually. The more fortunate medical technicians might have a limited automatic patient identification system. For example, in a Coulter STKR, the position of a tube inserted into a cartridge can be automatically identified by the machine. However, manual records matching patient names to sample numbers are

necessary. A hematology system should to be capable of automatic patient identification without requiring the user to handle clumsy labels.

Data Management

The medical technicians in the focus group also desired a hematology system that could intelligently interact with the user and with other chemical instruments. They wanted the machine to flag abnormal test results, inform them of errors with explicit words rather than with number codes, store quality control information, and perform other tasks to reduce any mundane but necessary effort. They wanted a "friend" that would effectively inform them of any tasks that they need to perform, provide results with their preferred formats, and communicate with laboratory information systems (LIS) and with other laboratory machines such as chemical analyzers. In general, the medical technicians expressed a need for simple and user-friendly features that would allow effective and efficient interaction.

Information storage was also mentioned several times during the focus group session. The medical technicians and laboratory supervisors were interested in having an information storage system capable of storing two days worth of blood analysis results, quality control (QC) data, and maintenance procedures and schedules. They suggested installing a disk drive in hematology analyzers to electronically store data for paperless data management because paper, in a clinical laboratory environment, can easily get lost, damaged or contaminated.

Menu

The blood parameters that the focus group partcipants expect from their hematology machine include reticulocyte counts, 5-part white blood cell differential counts, and red cell distribution width. The Sysmex R1000 and System NE8000 are machines distributed by the Baxter Diagnostics that can perform reticulocyte counts and 5-part differentials respectively. Red

cell distribution width (RDW) is available in most impedance-counting hematology systems.

BD is currently developing a method to perform reticulocyte counts using the QBC® technology. Information about BD's intentions for adding 5-part differentials and sedimentation rate is not available at this time. The QBC® technology, unlike the impedance counter which relies on individual cell counts, does not require the RDW because cell counts are made from distinct cell layers.

Disadvantages of Reagents

The impedance-counting machines require a lot of reagents. The reagents are toxic and expensive, have a short shelf-life, often get contaminated, and form sediments and crusts. Their packaging is bulky, hard to open, and wasteful because they do not allow dispensing of all the reagent. The focus group members expressed a desire for better packaged and less expensive reagents. However, the QBC® machines will not require any of these external reagent units since all the reagents are pre-coated in the QBC® tubes.

Overall System

The focus group wanted a hematology machine that is fast, inexpensive, easy to use, safe, quiet, looks "hi-tech", and modular for future upgradability.

A Star Trek Enterprise Hematology Analyzer

After 1-1/2 hours, Warren took a different approach to induce creativity in the focus group. He asked the participants to visualize themselves as medical techicians on the Star Trek Enterprise and explain the hematology machine that would exist in that scenario. This humorous

exercise was helpful in defining some unique customer demands and wishes as outlined in table 2.3.

The Star Trek Enterprise hematology machine was described to be a small intelligent interactive robot dedicated to automatically collecting and analyzing blood. It was also self-powered by a battery or the sun. Several focus group members were interested in watching the interior mechanisms through a clear skin during blood analysis.

BLOOD ANALYZER ON THE STAR TREK	
- Streamlined	- Compact
- Light	- Fits on Countertop
- Automated	- See-Through
- Smaller Reagents	- No Tubing
- Status Words	- Color Screen
- Takes Blood	- Talks
- Cheap	- Portable
- Does Billing	- Eliminates Serviceman
- Host Computer	- Battery or Solar Powered
- Automatic QC/Calibration	

Table 2.3 Hematology Machine on the Star Trek Enterprise

Immediately after the focus group session, the MIT team met with Warren for his feedback. He suggested that BD should sell benefits and not the technology. This idea appears to have merit since the medical technicians do not really care how blood is analyzed, whether by impedance-counting or centrifugation, as long as their needs are met. Low cost (system and disposable costs), low maintenance, and increased throughput are critical for sales. Warren believes that users want an interactive system that emphasizes ease of use. The lack of apparent interest in accuracy is mainly due to the fact that accuracy is *expected to be an inherent feature* of the system. The other expected functions of a hematology analyzer are the

measurement of blood parameters such as reticulocyte counts and 5-part white blood cell counts.

After the focus group session, our team held a meeting to decide how to use the information collected from the focus group, given that its members had only discussed issues regarding our *competitors'* products, which use a completely different technology than the technology that we are using. The marketing student and professor explained that we need to interpret the problems that the current products have and relate them to our new product. For example, customer complaints such as "aerosols are bad" (when aspirating or opening blood tubes) can be interpreted for the QBC® Walkaway machine as a need to eliminate aerosols caused by blood tube breaking during centrifuging. Other comments and experiences can be used to differentiate the QBC® product. Complaints such as "too much tubing for reagents and waste" are not relevant to QBC® technology; plastic tubing, used as conduits for blood, reagent, and waste transportation, is present only in the impedance counter technology. Thus, the QBC® technology, which requires no tubing, has a competitive advantage. Each of the issues addressed by the focus group members can be interpreted for the purpose of defining our design criteria.

2.4 House of Quality

The "House of Quality" (HoQ) is the first of four "houses" of QFD.[15,16] It provides a means of integrating customer voices and engineering design attributes. The other "houses" are briefly explained in section 2.4.7. HoQ is used with a multi-disciplinary product development team consisting of design engineers, manufacturing engineers, and marketing personnel. Constructing the house promotes active interaction among the members of the product development team. This enhanced communication prevents misunderstanding of each team member's function and reinforces the common goal of developing a product.[17] During the development process, HoQ functions as a design guidemap.

Our product development team constructed an HoQ for the QBC® Walkaway system (Figure 2.2-located in the back of this thesis) near the beginning of the design phase. The components of our HoQ are as follows (see Figure 2.3):

- Determine **customer needs** from market research
- Rank them according to **relative importance** as evaluated by the customer
- Evaluate **customer perception** of QBC® and competitors' hematology instruments
- Translate customer needs into **engineering design requirements**
- Develop a **relationship matrix** between engineering design requirements and customer needs
- Evaluate the inter-relationships of each engineering design requirement in the **roof matrix**
- Rank the **relative technical difficulty** of each engineering design requirement
- Rank the **relative technical importance** of each engineering design requirement

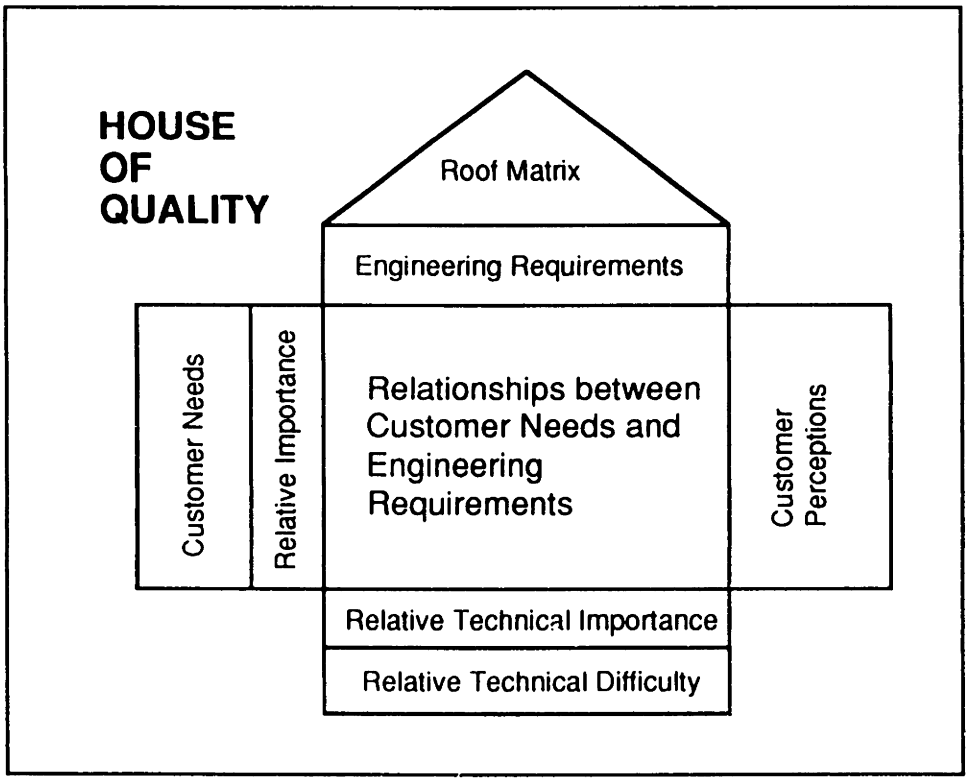


Figure 2.3 "House of Quality" of QFD[18]

Each of these steps will be explained in detail in the following sections.

2.4.1 Customer Needs and Their Relative Importance

Card-sort interview results were analyzed, and the relative importance of the 61 customer needs were determined (see left side of Figure 2.2 and Appendix C3).[19] The market segments that the team interviewed were medium-sized physician group practices (3-10 physicians) and hospitals. Rich Wong provided three different sets of index ratings by classifying the responses according to different groups: physician group practice medical technicians, hospital medical technicians, and both combined. His thesis provides an analysis of the variations of importance weightings between the two market segments.

The index ratings of the customer needs were analyzed and the ten most important medical technician needs from the physician group practices, hospitals, and combined are shown in tables 2.3, 2.4, and 2.5 respectively.[20] The combined index rating is the average of the physician practice and hospital index ratings. An index rating of 100 can be translated as average importance. Both market segments were studied because BD's original intention was to target both segments. However, as of January 1993, BD has decided to focus only on the medium-sized (3-10 physicans) practices .

Importance Rank	Index Rating	Customer Need
1	174	2) Achieves level of accuracy equivalent to Coulter STKR.
2	166	19) Accuracy even if the blood clots
3	159	5) No opening sample tubes
4	156	10) Machine that can be stopped for a RUSH job or emergency CBC ("STAT")
5	152	13) Low sample volumes for automatic testing
6	150	3) Analysis CBC time less than a minute
7	141	15) Eliminate opening tubes to solve aerosol problem
8	138	7) Performs repeat test automatically
9	133	33) Not spending a lot of time getting machine started up
10	130	6) Reads data and determines whether automatic repeat of abnormals necessary

Table 2.4 Ten most important needs for physician practice medical technicians

Physician practice medical technicians prefer an accurate, safe and automatic hematology machine (Table 2.4). The first two most important needs relate to accuracy. Coulter STKR is known by medical technicians to provide accurate CBC's; however, its nominal accuracy is not guaranteed when blood clots are formed in the machine. The 3rd and 7th most important attributes -- "no opening sample tubes" and "eliminate opening tubes to solve aerosol problems" -- raise the issue of safety. Physician practices often do not have the facilities to accommodate a full laboratory to perform chemical and blood analyses; most practices send samples or their patients to outside laboratories. Those that have an in-house lab usually perform 30-80 CBC's per day. This implies that medical technicians in a physician practice come in contact with blood relatively less frequently, in

contrast to hospitals that perform several hundred CBC's per day. Thus, they would tend to be reluctant to expose themselves to potentially hazardous blood samples. The 4th most important need is "STAT" capability; the capability to stop the machine's operation in order to *rush* a CBC of a critical blood sample. The next most important need is "low sample volumes for automatic testing", which is probably influenced by the goal to minimize blood sample volume requirement for pediatric patients. The last of the most important customer needs are throughput of less than 1 minute for a CBC, and automated features to expedite machine start-up and to repeat tests for abnormal samples to check for consistency.

Importance Rank	Index Rating	Customer Need
1	178	14) Able to throw specimens in cassettes, hit a button, and walk away
2	164	10) Machine that can be stopped for a RUSH job or emergency CBC.
3	152	2) Achieves level of accuracy equivalent to Coulter STKR.
4	147	3) Analysis CBC time less than a minute
5	147	44) Complete interface capability to information system
6	144	31) Results that are flagged when abnormal results come up
7	142	49) Ability to interpret QC information and recognize drift
8	142	56) Contains alternate technology for backup testing
9	139	47) Eliminating error codes and using words that tell you what's wrong
10	138	45) Able to store QC information

Table 2.5 Ten most important needs for hospital medical technicians

Hospital laboratories, in contrast to physician laboratories, usually perform several hundred CBC's per day as well as many other chemical and blood tests. Their major needs are "walkaway" capability, "STAT" capability, accuracy, speed, and information flow and storage (Table 2.5). "Walkaway" capability allows the medical technicians to perform other tasks while CBC's are generated. "STAT" capability is necessary because there are a large number of requests for immediate CBC's from emergency rooms and from doctors who suspect serious diagnosis of their patients. The need to perform large numbers of CBC's and "STAT's" require fast

hematology analyzers. Also, medical technicians would like to have the machine automatically flag abnormal results so that the sample analyses can be repeated or smeared on slides for visual inspection. Moreover, the immense numbers of analyses create the need to automatically recognize drift and maintain quality control information.

Importance Rank	Physician Index Rating	Hospital Index Rating	Combined Index Rating	Customer Need
1	174	152	163	2) Achieves level of accuracy equivalent to Coulter STKR.
2	156	164	160	10) Machine that can be stopped for a RUSH job or emergency CBC.
3	123	178	151	14) Able to throw specimens in cassettes, hit a button, and walk away
4	150	147	149	3) Analysis CBC time less than a minute
5	152	135	144	13) Low sample volumes for automatic testing
6	119	142	131	49) Ability to interpret QC information and recognize drift
7	138	119	129	7) Performs repeat test automatically
8	159	97	128	5) No opening sample tubes
9	166	88	127	19) Accuracy even if the blood clots
10	108	139	123	47) Eliminating error codes and using words that tell you what's wrong

Table 2.6 Medical technicians' ten most important needs in both physician and hospital markets

Table 2.6 lists the ten most important needs for the medical technicians in both physician and hospital markets. Most of the important needs of this combined market are similar to the two individual markets; they are accuracy, "STAT" and "walkaway" capabilities, quick CBC analysis time, and low sample volume. However, there are some needs that indicate disparities in importance weights between the physician group practice and hospital medical technicians. An example of this contrast deals with exposure to blood as shown below.

Physician	Hospital	Customer Need
141	99	(15) "Eliminate opening tubes to solve aerosol problems"
159	97	(5) "No opening tube samples"
125	105	(17) "Eliminate need to wipe aspirator tip".

Our interpretation is as follows:

Hospital medical technicians are not as concerned about opening tubes, wiping aspirator tips, or exposing themselves to blood aerosols, apparently because they are more familiar with blood handling safety practices. However, physician practice medical technicians take a more cautious view. Since they are less familiar with handling blood, they would rather avoid such potentially hazardous activities, if possible.

Another example of a large difference in relative importance of a need is in "accuracy even if the blood clots." A blood clot in an impedance-counting machine usually requires maintenance. Medical technicians in hospitals seem to be more familiar with machine maintenance than those in physician practices; a hospital machine's large workload probably requires frequent maintenance. Moreover, hospital medical technicians also tend to be more comfortable in dealing with exposed fluids, as previously noted. Thus, accuracy even if the blood clots is desired more by the physician practices and is not much of an issue in the hospital laboratories. Refer to Rich Wong's thesis for more analysis results.[21]

After analyzing the results from the card-sort interviews and attempting to understand the two market segments, the 61 customer needs were structured using *affinity-charts* or *K-J diagrams*. The affinity-chart process was used to impose a hierarchical structure onto the customer needs.[22] Our team classified the 61 customer needs into primary, secondary, and tertiary need categories. This categorization preserved the original customer importance rankings derived from the card-sort analysis. The primary need categories provide general descriptions of the customer needs. The secondary need categories divide the primary need categories into more specific groups. Finally, the tertiary needs are the basic customer needs.

These needs were placed in the left side of the House of Quality along with their respective importance ranks for the physician practice, hospital and combined market segments (see left side of figure 2.2 and 2.3).

A better method of developing a structured hierarchy would be to use the customer-sort process.[23] In a customer-sort, *customers* are given cards and asked to sort them in piles that represent similar needs. After sorting, each customer is asked to select from each pile a single card, called an *exemplar*, to represent the pile. The team can use the data from these interviews to create a co-occurrence matrix to develop a structured hierarchy of customer needs.[24] This study conducted by Griffin and Hauser concluded that "the customer sort hierarchy provided a clearer, more-believable, easier-to-work-with representation of customer perceptions than the affinity charts." This process could have been performed in lieu of affinity charts by the marketing team members if more time had been available.

2.4.2 Customer Perceptions

Customer perceptions describe how customers perceive the current BD product (QBC® Autoreader) in comparison with the competitors' products, in terms of satisfying their needs (right side of figures 2.2 and 2.3). The team rated (on a scale of 1 to 5) the customer perceptions of the QBC® Autoreader, and of a mid-range electronic cell counter, the Coulter model T540 based on our knowledge and experience from customer interviews. This comparison provides the opportunity to identify the desired attributes of the QBC® Walkaway system that may help to meet or exceed the current customer perceptions of hematology analyzers.

In meeting the most important needs, the Coulter T-540 is perceived to be better. It markedly outperformed the QBC® Autoreader in accuracy, "STAT" capability and CBC analysis speed. The main drawback to speed and "STAT" capability of the Autoreader is its dependence on a centrifuge for blood cell separation. The centrifuge takes 5 minutes to spin and it cannot be interrupted and restarted. Both machines were perceived well in requiring small sample volumes. However, the lack of automated features

such as "walkaway" capability, flagging abnormal results, automatic repeat test and automatic QC drift recognition in both systems resulted in negative customer perception.

The Autoreader was well perceived by our team in other less important categories such as maintenance, reagents, size and cost. It requires negligible maintenance and few extra maintenance costs, because there are no tubing and other blood contacting components that need to be regularly maintained by the medical technicians and servicemen. The system does not require any external reagent units since all the necessary reagents are pre-coated in the QBC tubes. The combined centrifuge and Autoreader are about a quarter of the size of a T540 and costs about $10,000 less than the T540.

2.4.3 Engineering Design Requirements

In the next step, the team translated the customer needs into engineering design requirements (located above the relationship matrix--see figures 2.2 and 2.3). The engineering design requirements were described in measurable terms. For example, the customer's need to "analyze a CBC in less than a minute" can be translated into engineering design requirements: centrifuge "spin time," tube "scanning time," "analysis time," and "material handling time." In these design requirements, *time* is a quantifiable term that can be used to interpret the specific customer need to analyze a CBC in less than a minute. Unquantifiable engineering requirements make generating objective design measures awkward. Thus, it was important for us to identify more quantifiable engineering design requirements to best represent each customer need. Examples are shown in table 2.7.

Customer Needs ---------->	Engineering Design Requirements
27) Machine covers that are easy to remove	• time to remove cover • number of steps to take apart for repair • height, width, and depth of the machine
18) Eliminate error in patient ID	• number of human failure points • amount of info. on tube • level of redundancy • labeling time • ID system cost • read and process time for ID
45) store QC information	• data storage capacity • number PCresources and functions used • number of external access routes
40) eliminate weekly or long-term maintenance	• weekly cleaning time • mean time for preventive maintenance • downtime for preventive maintenance
52) 24-hour service available	• repair time • 24-hour maintenance contract availability • mean time between failure • leadtime for repair
3) analyze CBC in less than a minute	• centrifuge spin time • scanning time • analysis time • material handling time • read and process time for ID • (result) print out time

Table 2.7 Examples of translations from customer needs to engineering design requirements

Some customer needs were difficult to translate into useful quantifiable engineering design requirements. The need for "simplified manuals with clear pictures and directions" was translated into the design requirements "steps per illustration" and "number of illustrations." It is difficult to determine the specific number of illustrations or number of steps per illustration which will make a manual "simple." In this case, rather than trying to quantify this particular need, the team decided to specify that the content and structure of operation and maintenance manuals will be designed to be as simple and clear as possible. We intend to research a variety of

product manuals to gain insight on the types of instructions that can best be conveyed to the users.

2.4.4 Relationships Between Customer Needs and Engineering Design Requirements

After developing the engineering design requirements, the team established relationships between the customer needs and the engineering design requirements in the "relationship matrix" (see figures 2.2 and 2.3). The purpose of this exercise is to understand how an engineering design requirement influences the customer needs. For example, the engineering requirement "number of human failure points" clearly has a strong relationship with the customer need that it was originally translated from, "eliminate error in patient ID." However, the same engineering requirement also strongly influenced the customer need to "load cassette, hit button, and walkaway," because improperly loading a cassette is a human failure point that can prevent system operation and possibly cause harm to the machine and to people. These types of correlations came from team experiences and from knowledge of hematology products and customers. We arbitrarily used "5," "3," and "1" for strong, medium, and weak relationships, respectively. If there was no relationship between a customer need and an engineering design requirement, the corresponding matrix element was left blank. These numbers were then used in conjunction with the index ratings of customer needs to determine the relative technical importance of each engineering design requirement. This procedure will be described in an upcoming section.

A important customer need, "stop for STAT" capability, stimulated a lengthy discussion among the team members. It was the second most important attribute for both the physician and hospital markets, and it strongly affected the engineering requirements of "spin time," "scanning time," and "analysis time." "STAT" has different interpretations; based on our customer interviews, the time for "STAT" results was determined to be anywhere between immediate and a couple of hours. According to BD

marketing personnel and doctors Levine and Wardlaw (the QBC® technology inventors), we learned that "STAT" duration is defined to be within about one hour. This news brought relief, because the QBC® system's speed is limited by an uninterruptable 5 minute centrifuge spin time; interrupting a batch during centrifugation can jeopardize the blood cell layer formation and result in erroneous analysis.

Although the customer's responses were based solely on their experiences with impedance-counting technology, many of their needs would be the same for the QBC® technology. But the needs which were specific to the impedance-counting machine were translated by the team into needs for the QBC® machine and they are presented in table 2.8. For example, "no opening sample tubes" is equivalent to "no opening Vacutainer Tubes for venous samples." Other examples, such as needs (17) and (32) relating to aspirator tips of impedance-counting machines, were associated with the thin capillary blood tubes used by QBC® machines. In addition, some customer needs that related to reagents and tubing would already be satisfied since the QBC® machines do not require any external reagent units or tubing. Our tailored customer needs permitted us to complete the relationship matrix that was appropriate for the QBC® Walkaway system design.

The engineering and marketing team members spent many hours together to complete the realtionship matrix. Developing the relationship matrix stimulated discussions and improved our understanding of the machine's design requirements translated from customer needs.

Customer needs for impedance-counting machines	Translations to customer needs for QBC® machines
5) no opening sample tubes	5) no opening of Vacu-tainer Tubes for venous samples
15) eliminate opening tubes to solve aerosol problems	15a) eliminate opening Vacu-tainer tubes to solve aerosol problems 15b) eliminate aerosols when a tube breaks during centrifugation
17) eliminates need to wipe aspirator tip	17) eliminate need to wipe capillary and venous capillary tubes
19) accuracy even if blood clots	19) accuracy even if blood clots in tube
20) eliminates the problem of machine jamming with blood clotting	20) eliminate the problem of machine unable to read with blood clotting (similar to 19)
25) uses little reagent and tubing	QBC® machines already meet this need because they don't use external reagent units or tubing
32) aspirating tip or probe that won't snap off	32) capillary blood tubes that won't break
34) equipment cleans and bleaches itself	34) QBC®'s optical measurement system cleans itself
35) reagent doesn't crust up	QBC® machines already meet this need because they don't use external reagent units
36) low reagent warning	QBC® machines already meet this need because they don't use external reagent units
37) elimination of reagent	QBC® machines already meet this need because they don't use external reagent units

Table 2.8 Translations of customer needs for QBC® machines

2.4.5 Roof Matrix

The roof matrix shows the level of interaction between each engineering design requirement (see the triangular roof in figures 2.2 and 2.3) and identifies sets of design requirements that might require more engineering attention. "M", "m", or "o" above each design requirement

points out, respectively, that increasing, decreasing, or setting a single target for its measure is desirable. Symbols were used in the roof matrix elements to represent relationships: two concentric circles denotes a strong positive relationship; one circle -- a weaker positive; double "x's" -- strong negative; and single "x"-- a weaker negative.

A positive relationship means that optimizing one design requirement will affect another design requirement advantageously. Increasing the "amount of information on tube" has a strong positive effect on decreasing the "number of human failure points." Similarly, a negative relationship indicates that optimizing one design requirement will negatively impact another design requirement. Increasing the "amount of information on tube" would most likely require more "labeling time," and therefore, a strong negative correlation exists between these design requirements.

Although increasing the "amount of information on tube" is disadvantageous to decreasing the "labeling time," it is advantageous to decreasing the "number of human failure points." Increasing the "amount of information on tube" undermines the ability of the designers to optimize other design requirements. This conflict should be prudently resolved by the engineering team by considering relative technical importance and difficulty, time constraints, human and financial resources, and any other corporate requirements. Having evaluated that a set of conflicting requirements are important to meeting customer and corporate needs, the team may design one or more features into the machine to eliminate the potential areas of conflict. Our team has not yet performed these detailed evaluations; however, it is recommended if time and resources are available.

2.4.6 Relative Technical Importance and Difficulty

Relative technical difficulties of meeting engineering design requirements were determined from team experience and knowledge (see bottom section of the houses in figures 2.2 and 2.3). A scale from 0 to 5 was arbitrarily selected and used to indicate the relative ease or difficulty in meeting a design requirement. Design requirements such as "number of

steps before walkaway" and "accuracy, precision, and repeatibility" were given 5's. Decreasing the "number of steps before walkaway" will require more automation ,and increasing "accuracy, precision, and repeatability" will probably require new technology; these requirements are clearly technically challenging. Design requirements such as decreasing "cassette size" only received a 2 because it probably would require minimal engineering effort; overall dimensions need to be minimal, but at the same time the cassette should be designed for handling. We considered many engineering parameters, such as technological availability, mechanical complexity, speed and level of computer control, in order to place a realistic technical difficulty level on each engineering design requirement.

The relative importance of each engineering design requirement can be detemined by multiplying customer index ratings to its correlation strengths in the relationship matrix and summing all these numbers down a column (see the bottom section of the house in figures 2.2 and 2.3). The HoQ in figure 2.2 provides the sums as well as the normalized relative importances (on a scale from 0 to 7) for the medium-sized physician practice, hospital, and combined market segments.

The most important design requirements (with normalized relative technical importance levels of 4 or more) are listed in table 2.9. There are essentially 5 categories of design requirements: "walkaway" capability, back-up tests using alternate technology, ease of maintenance, minimal exposure to blood, and data management. The relative importance of these design requirements for the physician, hospital, and both combined are quite similar so the following qualitative analyses of these design requirements will be for all three market segments.

"Walkaway" capability includes the following design requirements:

- increase variability of batch sizes
- reduce number of steps before walkaway
- reduce number of steps on return
- reduce required time before loading
- reduce number of human failure points
- reduce material handling time

Engineering Design Requirements	Phys.	Comb.	Hos.
increase variability of batch sizes	4	4	4
reduce number of steps before walkaway	6	6	6
reduce number of steps on return	4	4	4
reduce required time between loading	4	4	4
include password for supervisor	5	5	6
include alternate technology	5	5	6
reduce time for maintenance	5	5	5
increase automatic maintenance level	4	4	4
reduce number of human failure points	6	7	7
reduce material handling time	4	4	4
reduce downtime for preventive maintenance	4	4	5
reduce number of blood exposures	5	4	4
reduce number of aerosols	5	4	4
reduce number of times disposables handled	4	4	4
reduce number of sharps handled	4	4	4
increase data storage capacity	5	5	6
reduce number of PC resources and functions used	5	5	6

Table 2.9 Most important design requirements in physician practices, hospitals and both combined

As expected, the requirements for "walkaway" capability minimize interaction -- reducing time spent with machine, reducing the number of steps for operating the machine, performing automatic repeat tests when abnormal results are detected, and interfacing with LIS. Increasing "variability of batch sizes" includes the ability to perform just 1 ("STAT" jobs) or more CBC's. "Number of human failure points," translated from the need for eliminating patient identification error, has a strong relationship to the need for "walkaway" capability. It implies that minimal manual interaction with the machine system will reduce the chances for patient identification error.

The need for a back-up test using alternate technology is important for medical technicians when abnormal samples are encountered. The alternate test results are used to verify the original test results. Alternate technology for the QBC® Walkaway could, ironically, be an impedance-counting system. If a customer requires two hematology analysis technologies, purchasing both a Coulter and a QBC® machine might be an option. Or, if the customer already has an impedance-counting machine, the QBC® Walkaway can be used for back-up tests.

Maintenance is also an area of concern; its design requirements include:

- reduce time for maintenance
- increase automatic maintenance level
- reduce number of human failure points
- reduce material handling time
- reduce downtime for preventive maintenance

The impedance-counting machines inherently require a lot of routine maintenance for proper operation. Maintenance includes eliminating blood clots and cleaning tubing, both of which could affect machine accuracy. Moreover, there are large clumsy boxes of reagents for which expiration dates and fill levels need to be continually checked. Improper maintenance can be viewed as a human failure point that will lead to erroneous CBC results. However, the QBC® Walkaway should be able to easily meet these requirements because blood and reagents are enclosed in a blood tube.

Minimizing the opportunities for exposure to blood and aerosols, and for handling sharps (glass tubes, needles, etc.) are also design parameters that need serious consideration. These safety requirements are slightly more important to the physician practice medical technician than to those in hospitals, as expected from card-sort analysis.

The last category of design requirements relate to data management:

- increase data storage capacity
- reduce number of computer resources and functions used
- include password for supervisor

Customers desire the machine to store quality control information, CBC data, and on-board easy-to-follow maintenance instructions. Moreover, they would like to have the machine interface to LIS, recognize QC drifts, and flag abnormal results. Our team wants to be able to satisfy all these customer needs but at the same time we want to keep the Walkaway system's cost and size down by providing peripheral support capabilities with software and electronic data ports in lieu of costly internal computer peripheral hardwares. Passwords for laboratory supervisors for accessing quality control information and other supervisory controls can easily be incorporated into the machine software.

As anticipated, the important engineering design requirements relate very closely to most of the top ten customer needs identifed by the card-sort analysis (see section 2.4.1). Interestingly, accuracy and CBC throughput of less than a minute were not among the most important design requirements. Clearly, the design requirements that affect many customer needs receive high relative technical (engineering) importance. Unfortunately, as the team learned from the focus group (see end of section 2.3.2), accuracy was perceived by the customers to be an inherent feature of a machine and did not command a high level of interest. Customers usually point out features based on needs for operation and maintenance rather than features based on needs for blood analysis performance. Machine accuracy was mentioned by the customers with the need "achieves level of accuracy equivalent to Coulter STKR." Another need was "accuracy even if blood clots." But this need related to maintenance issues which influence the ability of the machine to perform its *expected function* of providing accurate results. Accuracy and other technological requirements should be specified as corporate requirements and added to the set of "customer" needs. For example, a corporate specification to increase speed, "faster analysis time," can be translated into the design requirements "increase computer processor speed" and "increase data collection rate." This addition to the left-side of HoQ might lead to a more well-rounded set of important design requirements.

If a machine's technological features are unknown, there are only a few ways to describe, say, the speed of CBC analysis. Customers did

exactly that when they simply asked for a "CBC analysis time less than a minute." This seemingly simple need was translated by our team into six different design requirements: "read and process time for ID," "analysis time," "spin time," "scanning time," and "material handling time." This one customer need leading to six design requirements created an *imbalance* in the ratio of customer needs to design requirements and undermined the importance for speed. In contrast, safety (from exposure to blood) had a ratio of 6 customer needs to 6 design requirements. Again, adding detailed corporate requirements in the list of customer needs might alleviate the imbalance problem of customer needs to design requirements, and help to generate a more thorough set of important design requirements. Moreover, requirements from other "customers" may be added to the list of customer needs:

- Regulations
  - Clinical Laboratory Improvement Act of 1988 (CLIA 88)
  - Occupational Safety and Health Administration (OSHA)
  - Underwriter's Laboratory (UL)
  - Federal Food and Drug Administration (FDA)
- Distributors
- Vendors
- The purchasing parties if not the end-users

2.4.7 Recommendations for Future Work

There are a few more components our House of Quality that have not been completed. At this writing, our team still needs to resolve conflicting engineering design requirements as they arise during the detail design phase (after the conceptual design phases which will be explained in the next two chapters). Another part of HoQ is objective measures, which compare each engineering design requirement, in quantitative measures, to our product and competing products.[25] Team consideration for these objective measures, such as relative technical difficulty, importance (from section 2.5.6), and estimated costs for fulfilling a design requirement, might be useful for developing an engineering target (eg. precision is less than 3%) for each design requirement -- which is the whole purpose of developing an HoQ.

The next phases continue with BD's product development team to construct more "houses" which convey the customers' voice to manufacturing (Figure 2.4)[26]. The second house develops the design goals and characterizes the system parts from the engineering requirements (parts deployment). The third house uses the parts characteristics to develop a set of key process operations for process planning. Finally, the fourth house generates production requirements based on key process operations for production planning. The team does not need to continually deal with large houses. Instead, a house can be broken down into several houses as long as interactions are minimized between the separated houses.

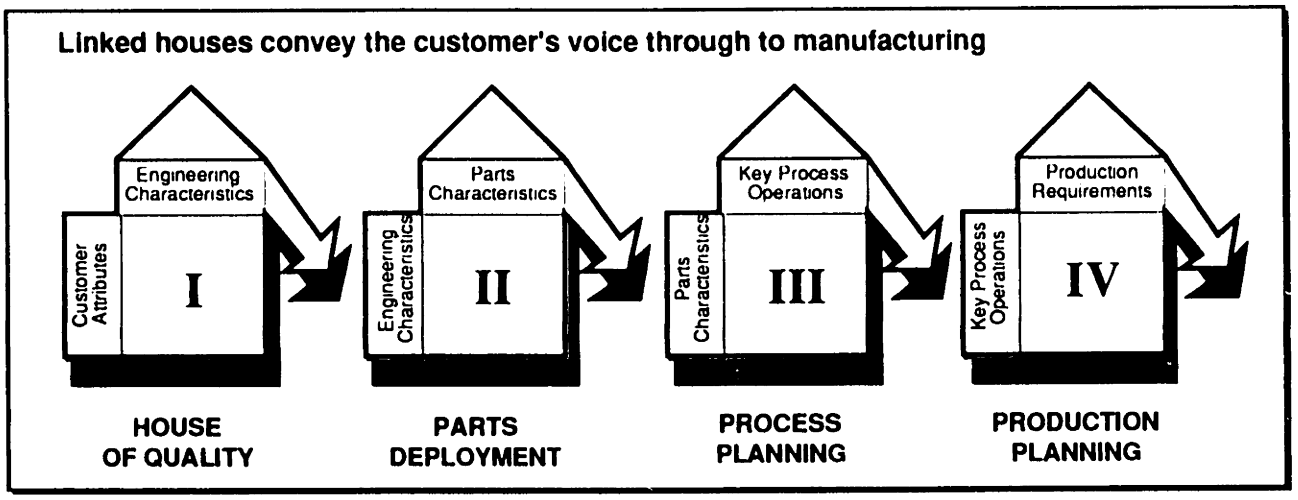


Figure 2.4 Four houses of QFD[27]

3. QBC® Walkaway Sub-System: Concept Generation Process and Results

The purpose of this chapter is to describe our product development team's approach to concept generation and selection. During concept generation, we generated up to 70 concepts for each of the four major sub-systems established for the QBC® Walkaway system. We then performed feasibility studies of the concepts. In selecting sub-system concepts, our team used a systematic concept selection process developed by Stuart Pugh.[28] The process incorporates design criteria such as engineering design requirements from HoQ, reliability, manufacturing, cost, and maintainability. By considering many issues associated with the QBC® Walkaway system during the concept design phase, we were hoping to ultimately develop a "strong" system that would require only minimal redesign work in the future. The implementation and results of this conceptual design process for the QBC® Walkaway will be presented in the next chapter.

There were essentially two stages in our team concept generation and selection process:

- Stage 1: The QBC® Walkaway system was divided into principal sub-systems and concepts for these sub-systems were generated and discussed by the team.

- Stage 2: Concept feasibility studies were conducted. Feasible concepts were then evaluated, assessed, and selected.

Our team also performed a preliminary failure mode and effects analysis (FMEA) which can be found in Appendix D1. Important procedural elements will be described throughout the chapter. Conclusions drawn from performing these tasks will be presented in the later sections of this chapter.

3.1 Stages to Concept Selection

3.1.1 Stage 1: Concept Generation

Our team had to decide on a brainstorming procedure. We had two approaches -- (1) generate a set of entire system concepts or (2) generate several sets of principal sub-system concepts. After some discussion, we concurred on the second approach because it would help us maintain focus on the *primary* system functions. *Secondary* sub-systems, such as tube handling mechanisms, were set aside for future evaluation because their designs were dependent on the *primary* sub-systems.

After Pugh concept evaluation, we had the intention to select combinations of the "strong" primary sub-system concepts to make three systems (see section 3.3 for final results). Figure 3.1 shows our *general approach* to creating three system from the results of our sub-system concept selection process:

System 1: A1, B2, C3, D1,
System 2: A2, B3, C1, D2,
System 3: A1, B2, C2, D2.

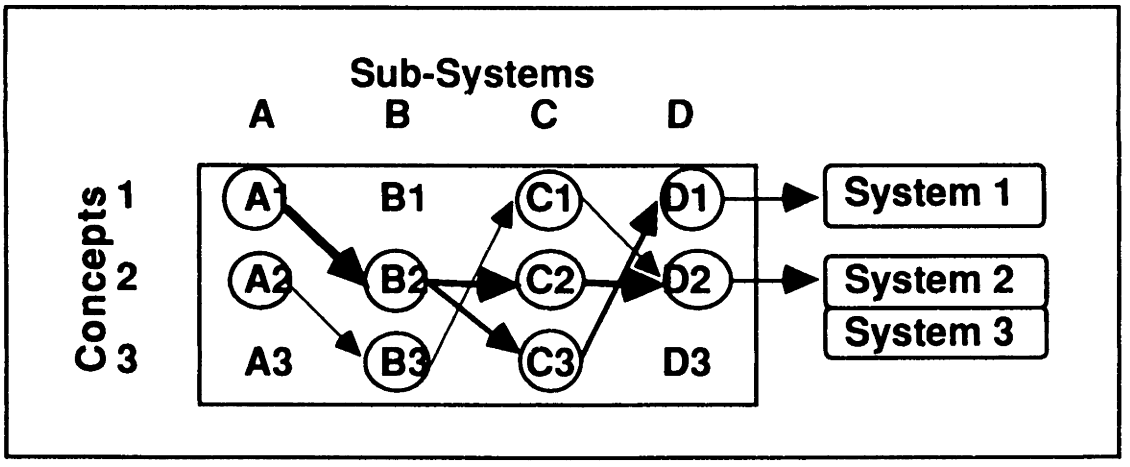


Figure 3.1 System selection from sub-system concepts

Our product development team performed numerous individual brainstorming drills and about 15 group brainstorming sessions, each lasting 3-4 hours. These brainstorming sessions involved marketing, electrical engineering, and mechanical engineering graduate students as well as the supervisors from each discipline. We presented concept drawings and their descriptions to each other, with the hopes of generating nearly 100 concepts for each primary sub-system functions. We were, in fact, able to generate between 40-70 ideas for each of these functions (see Table 3.1 and Appendix D2).

Machine Functions	number of ideas
Display CBC information	48
Cell separation	54
Measuring float and tube annulus	66
Measuring bands	62
Patient identification	44
Blood transfer to machine	21
Overall system configuration / Industrial design	20

Table 3.1 Preliminary brainstorming activities

The main sub-system functions that we established on were: "display CBC information," "cell separation," "measuring float and tube annulus," "measuring bands," and "patient identification" (Table 3.1).

- "Display CBC information" deals with conveying CBC results and suggested diagnoses to medical technicians and doctors.
- "Cell separation" deals with separating blood cells into its components. Currently, a centrifuge is used for this function, but we decided to look for other alternatives.
- "Measuring float and tube annulus" deals with measuring the annulus area created by the float outer diameter and the tube inner

diameter (Figure 3.2). The QBC® Autoreader measurement accuracy for white blood cell layers in the annulus is about 95% despite high manufacturing tolerances for both the float and the tube. BD's goal with the Walkaway system is to achieve accuracy greater than to 97%.

- "Measuring band" deals with determining the lengths L's of the blood cell layers after centrifugation (Figure 3.3). BD's goal for this axial measurement precision is 0.0005 inch.

- "Patient identification" deals with minimizing human errors in matching CBC results to the patients.

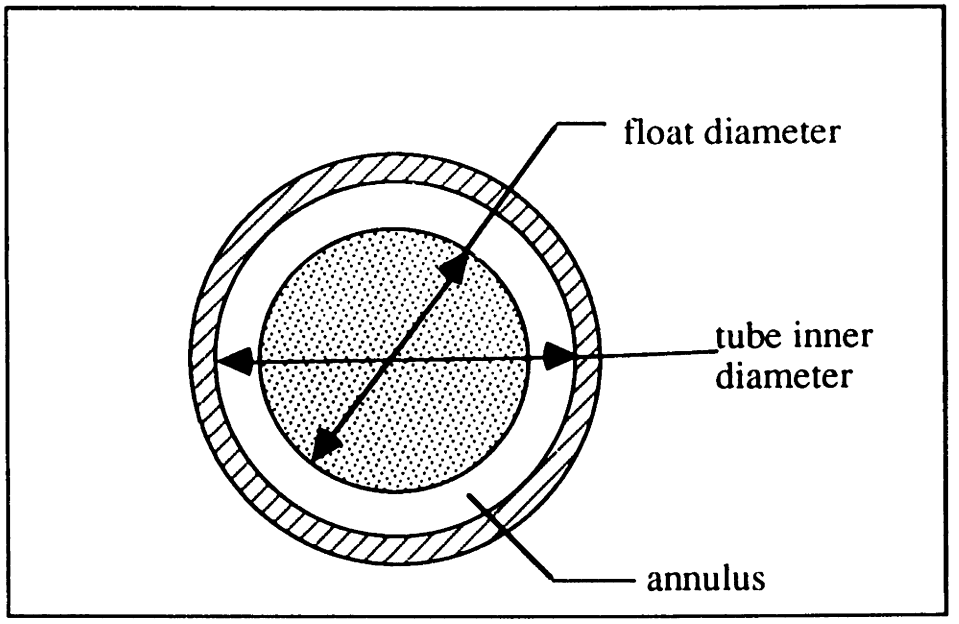


Figure 3.2 Tube and float annulus

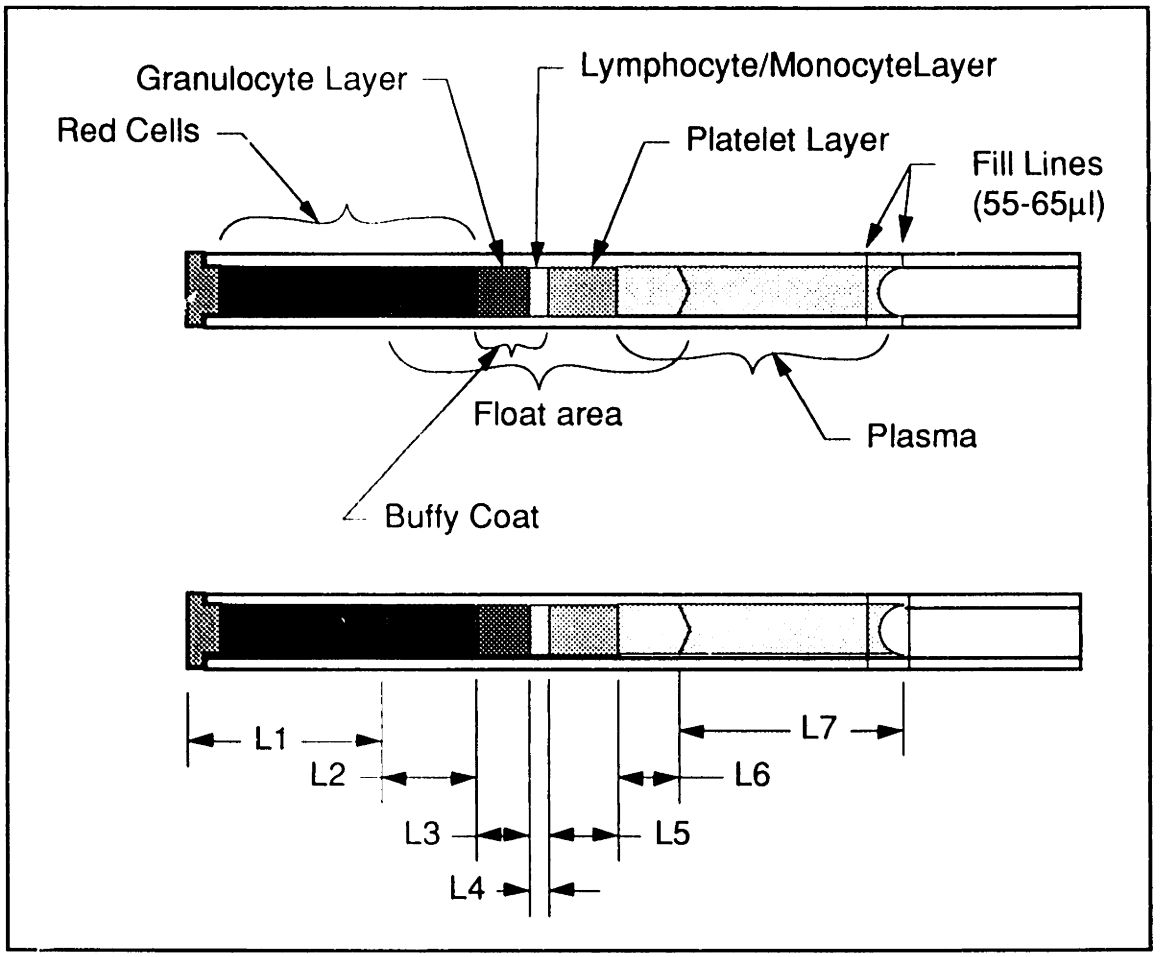


Figure 3.3 Blood cell layers

Concept brainstorming involved both individual and group effort. We selected one function at a time (Table 3.1) in which each individual team member generated about 10 concepts to present to the team. (The raw data is presented in Appendix D2.) We then brainstomed as a group. The sessions usually lasted only about a few hours per day, after which, our effectiveness in generating and discussing ideas deteriorated dramatically. During group brainstorming sessions, our team tried not to criticize eachother's ideas. Criticizing during brainstorming only hindered creativity and inhibited interaction by forcing team members to share only defensible concepts. The purpose of brainstorming has been to use the collective creativity, experience and knowledge of individual team members to stimulate the generation of new ideas.

Although our initial intention was to brainstorm primary sub-system functions, we were curious to see what kind of ideas the last two functions of Table 3.1 would evolve. "Blood transfer to machine" was a secondary sub-system function and clearly, "overall system configuration/industrial design" dealt with the overall system design. The results in Appendix D2 show that there were some interesting system ideas. For example, in "blood transfer to machine," we thought about eliminating handling blood tubes and letting the machine automatically take samples by directly putting the patient's arm into a slot or the patient's finger into a hole in the machine. Another related idea was to have a tube appendage on the machine that can draw blood directly from the patient using disposable needles. Brainstorming in these areas stimulated many new and interesting ideas which we intend to use during system concept development.

The "display CBC information" function is presented here as a typical example of our brainstorming process. Although most ideas dealt with displayed information, related functions such as human interface and data management also spawned. LCD screen, monochrome monitor, voice output, and color coded forms were among the function ideas. "Mouse-driven" interaction and "radio link between machine and doctor's office" were among the related function ideas. Quite often, our relaxed attitude to idea generation process aided in stimulating a lot of creativity.

In some cases, ludicrous ideas became catalysts for generating better ideas. During and after the exchanging individual ideas, new concepts were shouted out which often led to a chain reaction of more new ideas. There were also times when ideas "leap-frogged" during the brainstorming sessions. For example, while brainstorming "measuring (blood cell) bands," someone suggested : "tag cells with radioactive element and detect radiation." But after this, two other ideas relating to radiation followed: "expose tube to radiation then scan tube and measure radiation intensity" and "tag with radioactive element and measure the decay rate/half life". Then, several completely different ideas were mentioned after which someone returned to the radiation idea and suggested "(hey, let's use) radioactive tag and (detect with ...) an x-ray!!!". Using radioactive elements for blood analysis seemed very peculiar. Interestingly enough, the band

measuring method that we eventually chose, was analogous to this idea. Rather than using radiation, we eventually selected to measure blood cell bands by detecting the light emanating from blood cell using a linear CCD array.

3.1.2 Stage 2: Concept Evaluation and Selection

After the brainstorming sessions, each team member took the the responsibility to perform preliminary feasibility studies of all the concepts. Feasibility studies included finding out about the currrent technologies, performing technical analyses, doing literature research, and talking to experts (often vendors and BD engineers). For example: a study was conducted for determining the feasibility of using an ultrasound transducer to send ultrasonic sound waves axially into the tube and to receive reflected waves from each blood band. Library research was performed to better understand its technology. Blatek, Inc., manufacturers of ultrasonic transducers for our application, was then contacted. The company apparently has high precision liquid ultrasound transducers with frequencies ranging from 0.5 to possibly 10Mhz. The vendor explained that the axial resolution is approximately 1/4 the sound wavelength generated by the transducers. Using elementary equations and the speed of sound in blood (which is close to water) of 1.5mm/μsec, the axial resolution was detemined to be:

$$resolution(in.) = \left(\frac{1}{4}\right)\left(\frac{1}{frequency(Mhz)}\right)\left(1.5\frac{mm}{\mu\sec}\right)\left(\frac{1in.}{25.4mm}\right)$$

$$resolution(in.) = \left(\frac{0.014764}{frequency(Mhz)}\right)$$

Using the above equation, the range of achievable axial resolution was found to be between 0.030 to 0.0015 inch. This performance could not meet the 0.0005 inch resolution requirement and so the ultrasound was agreed to be and unacceptable concept for the Walkaway system.

After the feasibility studies, our team convened to assess each concept. We eliminated ideas that were not feasible and combined similar ideas. This process dramatically reduced the number of concepts to a manageable level of around 10 for the Pugh concept selection process. We agreed to continue to evaluate four sub-systems for the QBC® Walkaway machine: "patient identification," "measuring (blood) bands," "measuring float and tube annulus," and visual "display." The "cell separation" function was eliminated after we learned that BD experts had already experimented with many of our concepts in the past and found that they did not perform better than just simple centrifugation.

Feasibility studies allowed the team to evaluate ideas based on facts rather than on speculation. There were times during concept selection when we could not evaluate concepts because of lack of information. This slowed down the process since we had to conduct a more thorough investigation before concept evaluation could continue.

Pugh concept selection process

The Pugh concept selection process is a systematic method for selecting the concept that best meet engineering design requirements of the House of Quality and other design goals set by the team.[29] It is used extensively in MIT's undergraduate and graduate engineering design curriculum and is becoming more commonplace in many corporations.[30] In the section, the Pugh concept selection process and its results are presented.

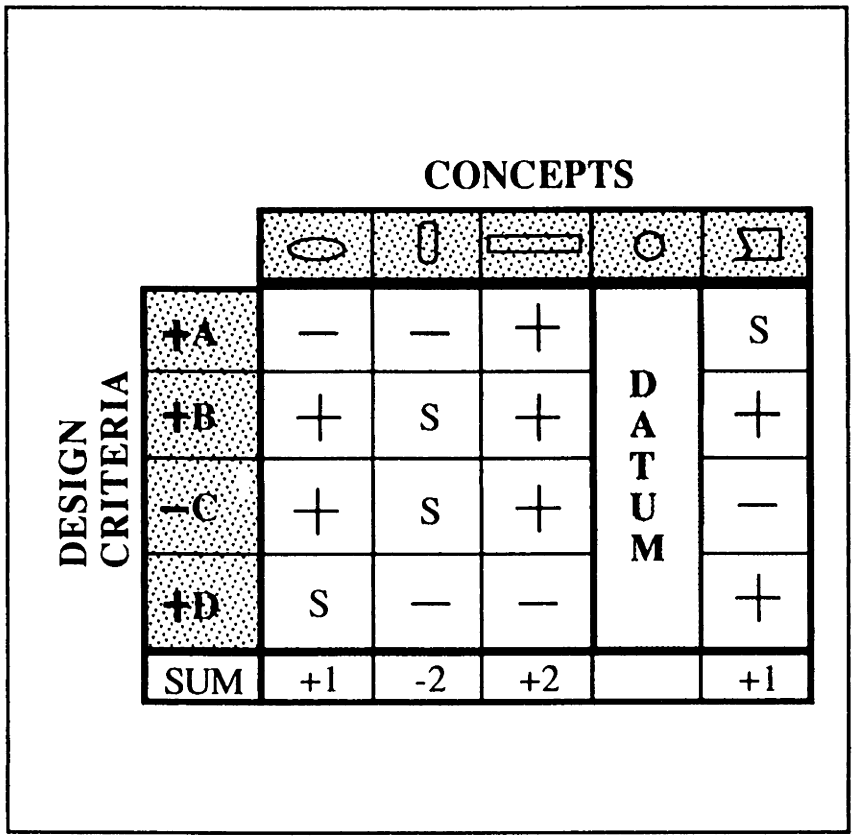


Figure 3.4 Sample Pugh Chart

1. Large poster papers (4 feet x 20 feet) were used to make the Pugh charts for each primary sub-system mentioned in the previous section: "patient identification," "measuring (blood) bands," "measuring float and tube annulus," and visual "display." A general Pugh chart is shown on figure 3.4 for reference. The large posters allowed every team member to easily refer to the concepts and design criteria during the evaluation and selection process.

2. Concept drawings and/or descriptions were placed on the top row.

3. The concepts were drawn and/or described on a similar level of detail in order to prevent bias of any one concept. Moreover, we agreed on a name for each concept to make communication easy.

4. A list of design criteria was made for each sub-system. These lists were generated from engineering design requirements of HoQ (see figure 2.2

and sections 2.4.3 to 2.4.6) that were relevant to the sub-system function and other design goals specific to the sub-systems. An example is presented to explain the details and importance of this process.

For "patient identification," there was one set of general criteria from the HoQ (engineering design requirements) and another set of more specific criteria related to its basic function (section 3.2.1):

Engineering design requirements for "patient identification"

- \- System cost
- \- Manual human interaction with tube and/or form
- \- Number of potential failure points from human interaction
- \+ Ability to interface to laboratory information system (LIS)

Other engineering design goals for "patient identification"

- \- Cost per sample
- \+ Machine can read ID
- \+ Ease of tube reading by human
- \+ Reliability in reading ID
- \- Potential ID interference with blood band and tube&float annulus measurement operation
- \- Laboratory information system (LIS) dependency

The "+" and "-" indicate that that *more* or *less* of a criterion level is better for the sub-system design. For the criterion, "machine can read ID," it is better to have a system with a *greater* multi-functional capability that can read ID as well as measure blood cell bands and tube & float annulus. In another example, it is better to *minimize* the patient ID system's "laboratory information system (LIS) dependency" because some customers do not have such systems. But at the same time, it is important to maximize the "ability to interface to LIS" because some customers already have or intend to install LIS in the near future.

Although many design criteria were obvious to indicate with a "+" or a "-," there were those that were not as obvious but we made decisions based on speculations. To our dismay, we learned the

importance of making careful decisions as the following situation shows. In the sub-system "display" (detailed in section 3.2.4), we indicated the "size of display" criterion with a "-" without much discussion. During the concept selection process, there were some long exciting debates among the team members. Some of us felt that smaller screens would suffice to display CBC information effectively, give minimum customizability with a touch keypad, and keep the machine cost down. Others felt that medical technicians would probably be willing to pay the higher cost for a larger screen that will make reading easier and give the screen more room for customizability. In the end, we decided to discontinue the "display" sub-system evaluation because we were not exactly sure what our *customers* wanted. We intend to continue this selection process after we obtain more customer input about displays. We learned from experience that understanding the design goals before beginning the Pugh selection process is important to help to expose areas where more market research was needed.

In another instance, "cost" was misunderstood by a couple of team members as being just material costs excluding manufacturing costs. When this misunderstanding was recognized while completing the Pugh chart, we reviewed the design criteria and repeated the entire concept selection process for that sub-system. We learned that common understanding of design goals and requirements was critical to the success of the process. Our presumptions wasted a lot of time but eventually we were fortunate to recognize the misinterpretations to help bring mutual understanding of each design criteria. However, this mishap could have been avoided by writing the detailed definitions next to each criterion on the chart.

5. A concept which the team members felt was "strong" and well understood was selected to be the datum. For example, for "measuring bands," we selected "HWH" (section 3.2.2) because we were already familiar with the technology (which was developed by BD) and we felt it had potential for the Walkaway system.

6. We evaluated across the matrix, one criterion at a time, and gave a "+", "-", or an "s" to each concept with respect to the datum. Going across prevented defensive attitudes from team members on a single concept and helped to maintain a consistent definition of the criterion. Each team member took turns mediating these evaluation sessions.

7. The "+", "-", and "s" were summed. We selected the concepts with the greatest number of "+" and from this selection. There were usually about 3 "strong" concepts per sub-system.

8. We then "attacked the -'s" of these selected concepts and started forming hybrids. Features of other "weaker" concepts and/or new concepts were used to eliminate those negative attributes. The level of conceptual detail generally increased with this procedure. Moreover, the process of forming hybrids induced more ideas.

> Although a concept might have a lot of +'s and s's, if it was not able to meet a critical design criterion such as 0.0005 inch precision for "measuring bands", one would say that the design is weak. Incorporating weights to each design criteria might eliminate this problem. However, it is quite difficult to weigh design criteria because they are very subjective. Forming hybrids eliminated these weights. When hybrids are made, -'s are changed to +'s and so the critical design criteria were considered. For example, the "HWH" (see section 3.2.2), which was found to be a "strong" concept, received a "-" for its inability to perform the necessary fluorescence readings because of its red laser. However, the "-" was changed to a "+" by suggesting the use of a blue rather than a red laser. As long as hybrids are formed and -'s were changed to +'s, subjective weighting of the design criteria was unnecessary.

3.2 Results of Concept Evaluation and Selection

Before beginning the Pugh concept selection process, we eliminated many ideas after the initial feasibility studies and we often combined many of the similar ideas. We narrowed the field of reasonable concepts down to 4 to 15 for each function. During the selection process, we set aside the weak concepts which generated a lot of -'s in the Pugh matrix, in order to expedite the often long and arduous sessions.

3.2.1 Patient Identification

"Patient identification" deals with associating a patient's blood sample with its analysis results. With the current QBC® systems, the user must manually keep track of a patient's sample in the numbered tube slots in the centrifuge rotor and while transferring to the machine after centrifuging. Hence, the possibility of identification errors made us consider patient identification systems meant to minimize user error and intervention.

We began by generating a list of patient ID selection criteria based on the HoQ and from our own intuitions (Table 3.2).

An important criterion was preventing interference with blood analysis. However, we did not want to leave out the possibility of using an ID reading mechanism to also measure bands and float & tube annulus.

Patient Identification Concept Selection Criteria
- 1. System cost
- 2. Manual human interaction with tube and/or form
- 3. Number of potential failure points from human interaction
+ 4. Ability to interface to laboratory information system (LIS)
- 5. Cost per sample (ie. disposable cost)
+ 6. Machine can read ID
+ 7. Ease of human reading on tube
+ 8. Reliability in reading ID
- 9. Potential ID interference with blood band and tube&float annulus measurement operation
- 10. Laboratory information system (LIS) dependency

Table 3.2 "Patient Identification" concept selection criteria

Interface capability to LIS was another desirable feature for the medical technicians. Although many customers of our target market do not have LIS, many have stated that they intend to incorporate such information systems in the near future. To satisfy both LIS users and non-users, we decided that the Walkaway system should be capable of interfacing and at the same time, be independent to LIS to maximize the machine's versatility.

Evaluated "Patient Identification" Concepts

After numerous (about 5) team meetings, discussions, and feasibility studies we concurred on 7 patient identification systems from a set of nearly 70 concepts for the Pugh concept selection process. These 7 concepts are shown in figure 3.5.

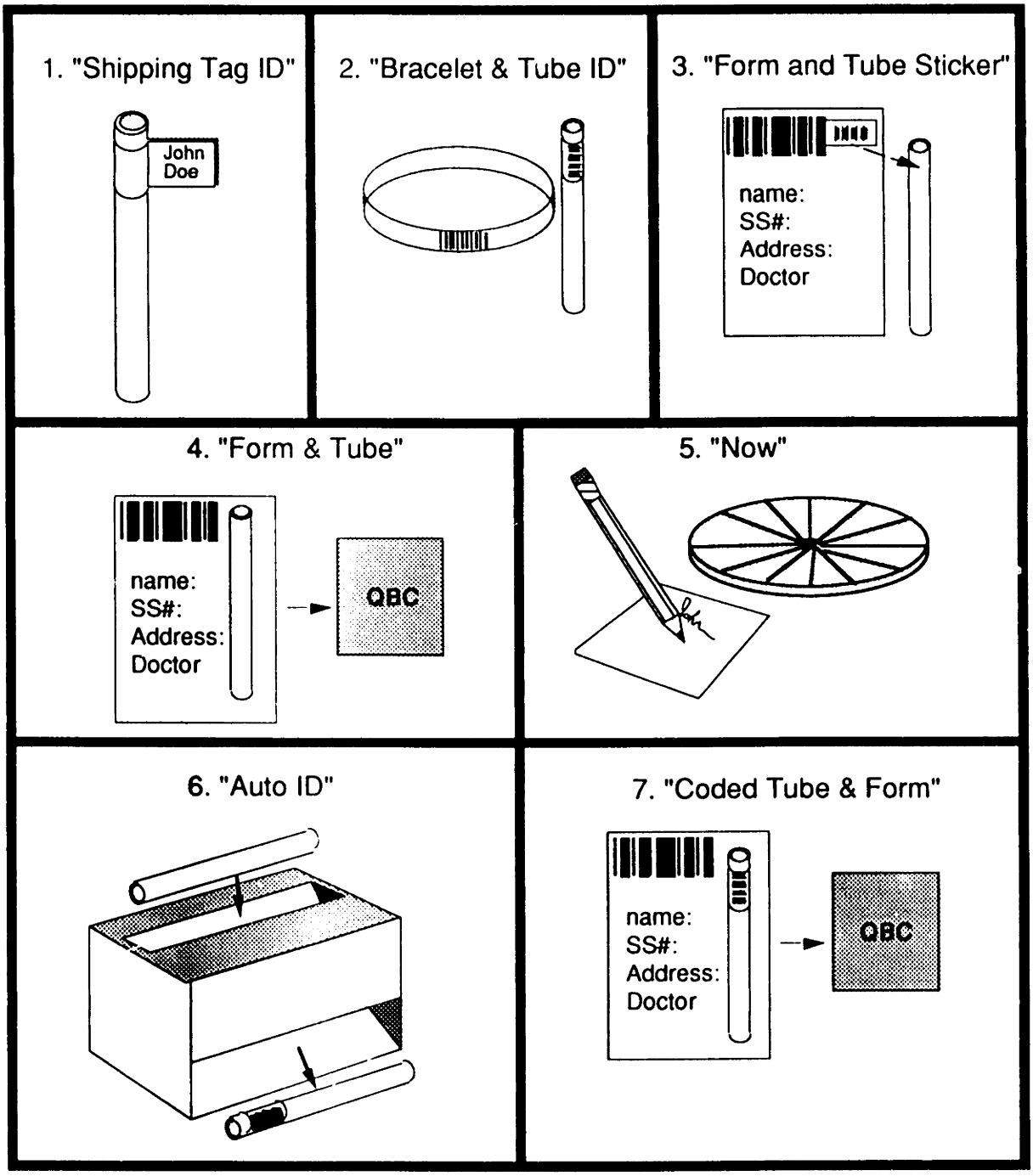


Figure 3.5 "Patient Identification" concepts

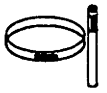
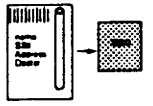
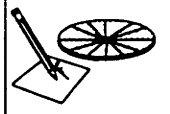
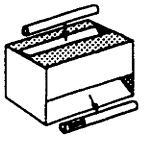
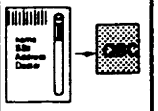
Patient Identification Concept Selection Criteria	1. "Shipping Tag ID" 	2. "Bracelet & Tube ID" 	3. "Form and Tube Sticker" 	4. "Form & Tube" 	5. "Now" 	6. "Auto ID" 	7. "Coded Tube & Form" 
- 1. System cost	+	S		+	+	-	+
- 2. Manual human interaction with tube and/or form	-	+	D A T U M	S	-	+	S
- 3. Number of potential failure points from human interaction	S	+		S	-	+	+
+ 4. Ability to interface to laboratory information system (LIS)	S	S		-	-	S	S
- 5. Cost per sample (ie. disposable cost)	+	+		S	+	+	S
+ 6. Machine can read ID	-	S		-	-	S	S
+ 7. Ease of human reading on tube	+	S		+	-	+	S
+ 8. Reliability in reading ID	S	S		S	-	+	S
- 9. Potential ID interference with blood band and tube&float annulus measurement operation	-	+		+	+	+	S
- 10. Laboratory information system (LIS) dependency	+	S		+	+	+	+
SUM	**0**	**+4**	**0**	**+2**	**-2**	**+6**	**+3**

Figure 3.6 "Patient Identification" Pugh chart

Refer to the Pugh chart on figure 3.6 for the following evaluations and results of "patient identification."

1. "Shipping tag ID"

A phlebotomist attaches a piece of handwritten tape or tag around the top of the tube. After inserting the tagged tube into the QBC® Walkaway, a medical technician types in the patient ID into the machine using a keyboard.

This concept does not require a costly ID system. The cost per sample is low because it only requires a simple tag. A handwritten tag makes it easy to read and also makes it LIS independent. However, the drawbacks are that it requires a lot of manual intervention and it increases the number of potential human failure points.

Score: 0 (scored same as the datum)

2. *"Bracelet & Tube ID"*

A phlebotomist associates a patient tag (such as a bar code on a bracelet or card) with a pre-coded tube (which could also be a bar code) by scanning in both of them after drawing blood. The tube is sent to the lab and the LIS automatically matches the blood analysis to the patient. The doctor can receive the blood analysis through his office computer by typing in the patient's ID number or scanning in the patient's ID tag.

The "Bracelet and Tube ID" fared well in cost per sample, not interfering with QBC® operation, low amount of human interaction with tube and form, and low number of potential failure points from human interaction. In the other criteria, this concept matched the datum. Unfortunately, it requires an LIS.

Score: +4

3. *DATUM: "Form and Tube Sticker"*

In this concept, a pre-coded (barcode) form also contains a corresponsing bar-coded sticker. A doctor removes the bar-code from the form and sticks it on a blood tube. After blood is drawn, the tube is sent down to the lab and the form remains with the doctor. The doctor can call up the blood count on his office computer by scanning the bar code on the form with a bar code"pen." This concept requires the use of an LIS.

Score: 0

4. *"Form and Tube"*

A pre-made form with a bar code, and a QBC® blood tube, that does not have an identification tag, moves around as a unit. After drawing blood, the medical technician simultaneously inserts the form and tube into their respective slots in the QBC® machine. The machine automatically maintains the association of the form to the tube. The results are printed out on the pre-made form.

Since the patient information is printed directly on a pre-coded form, reading the form and associating the sample to the patient is easy for the medical technicians. Furthermore, the lack of any identification tag on the blood tube eliminates interference with the QBC® blood reading operation. However, it can't interface with LIS unless the form can be scanned by an internal scanner *and* the medical technician types in the corresponding patient information.

Score: +2

5. *"Now"*

This is the current method of manually keeping track of tubes. The medical technician must record the location of the tubes in their respective centrifuge slots.

The need for manual interaction increases the possibility for erroneous patient identification especially with large batch jobs.

Score: -2

6. *"Auto ID"*

Before blood is drawn, a phlebotomist inserts a tube into an ID generator and types in the patient ID such as social security number, name, and patient's doctor. It automatically dispenses the tube with a human readable and QBC® machine readable identification tag. The phlebotomist immediately draws the blood from the patient. The ID generator can be attached to the LIS but needn't be. The blood tube is transferred to the lab and the LIS can automatically associates the analyzed tube with the patient. The patient's blood analysis is quickly forwarded to the doctor via the LIS or hand delivered.

The "Auto ID" concept was by far the strongest concept. With this patient identification system, the Walkaway machine can be configured to be LIS-dependent or independent. Since patient information is directly placed on a blood tube, which can be read by both the machine and the medical technicians, the possibility of accidentally associating a tube to a patient dramatically decreases. The only major drawback was high system cost.

Score: +6

7. *"Coded Tube and Form"*

A medical technician simultaneously inserts a pre-coded form and a pre-coded tube (both with the same bar code) into their respective slots in the QBC® machine. Since both the form and tube have the same bar code, they do not necessarily have to be placed into the QBC® simultaneously. This feature eliminates one potential human failure point.

This concept is very similar to the "Form and Tube" concept with the exception for the pre-coded tube. The QBC® machine can read the tube and has the option to download the blood analysis results and patient code to the LIS.

Score: +3

NOTE: For all these concepts, there could be an option to allow the medical technician to intervene, read the analysis results, and push a "GO" or "NO-GO" button before the analysis is forwarded to the doctor via LIS or manual transfer. The medical technicians from our interviews and the focus group session often asked for this intervening feature.

"Patient Identification" Evaluation Conclusion

The following four concepts beat the datum: "Bracelet and Tube ID", "Form and Tube", "Auto ID", and "Coded Tube and Form." The strongest concept was Auto ID with the only drawback being its potentially high system cost.

We re-analyzed each of the concepts and proceeded to form hybrids. We eliminated the "Form and Tube" concept after agreeing that this concept was quite similar to the "Coded Tube and Form" concept except for a coded

tube. We decided to conduct a more detailed feasibility study and also form hybrids of the three strongest concepts: "Bracelet and Tube ID", "Auto ID", and "Coded Tube and Form."

To gain a better understanding about identification systems, I contacted a vendor specializing in automatic identification, Symbol Technologies in Framingham, Massachusetts. Apparently, this vendor had experience with patient identification system in hospitals. She explained that hospitals are unwilling to spend money on a *dedicated* automatic identification system for a single medical instrument, especially if they intend to incorporate a *universal* automatic patient identification system that can be interfaced to all their medical instruments and electronic information systems. Unfortunately, both the "Auto ID" and the "Bracelet and Tube ID" concepts required a dedicated automatic identification system; the "Auto ID" required a machine to automatically encode and dispense QBC® tubes, and the "Bracelet and Tube ID" required a hospital-wide computer information system that provided ID bracelets or cards to patients. Her logical explanations allowed us to eliminate these two concepts. We then decided to form hybrids on the "Coded Tube and Form" concept.

Final Options

8. *A tube with 2 bar codes; one that is permanently affixed to the tube and the other larger bar code (with same ID as the permanent one on the tube) that can be peeled off to be attached to any form that contains patient information.*

   A medical technician uses a bar code reading wand, which is attached to the machine, to manually scan the bar code from the form after a tube has been analyzed by the machine. The machine associates the results from the pre-coded tube and the scanned-in bar code and automatically prints out the results on plain fan-fold computer paper. The printed results can be stapled or taped to the original form containing patient information. This idea eliminates the need for a dedicated pre-coded form and also makes the entire

system less expensive and simple. However, there is still the possibility of attaching the wrong tube's results to the patient's form.

9. *A pre-coded tube and form with a form feeder in the machine.*

   A stack of forms, each imprinted with a patient's information, is inserted into the QBC® machine. The forms are fed automatically into the machine and their bar-codes are automatically identified by a dedicated bar code reader. The machine associates a blood analysis with the correct pre-coded form and the results are printed directly on that form. The automatic form feeder and the dedicated bar-code reader can make this system more expensive but mis-association of results with patients due to human error is eliminated

10. *A hybrid of 8 and 9. A tube has 2 bar codes; one permanently affixed to the tube and the other larger bar code which can be peeled and stuck on any form. The QBC® system's printer is capable of reading the bar code stuck on the form.*

    After tube analysis, a medical technician feeds the form (with the bar code sticker) into an external dot matrix printer linked to the QBC® machine. This printer's head contains a photodetector which can read the bar code as it traverses across the form. The blood analyzer can then associate the bar code with the proper results and download the information to the printer. This idea eliminates the need for a dedicated form and an expensive integral automatic feeder and bar code reader. Moreover, it can be both inexpensive and eliminate a potential user-error associated with the original "coded tube and form" concept.

We decided that some form of hybrid of the "Coded Tube and Form" system concept would be most effective for patient identification. At this writing, we are not at a position to select a final concept. Patient

identification is a very important issue especially with increasing insurance costs and mal-practice suits. We intend to perform a focus group in the near future to help us to make a prudent selection of a patient identification system that best satisfies the customer and minimizes user error and interaction.

3.2.2 "Measuring Bands"

"Measuring bands" is the function for measuring the length of each layered blood component in a centrifuged capillary tube. Band measuring techniques must accommodate fluorescence as well as transmission readings (described in section 1.4). From these measurements, the QBC® system software can determine the blood cell counts and also provide suggested diagnoses (known as *diagnostic reminders* at BD).

"Measuring Band" Concept Selection Design Criteria
+ 1. Accuracy
+ 2. Precision
+ 3. Repeatability
- 4. Cost
+ 5. Reliability (Mean Time Between Failure)
- 6. Size
+ 7. Speed (Speed of Taking Measurement)
+ 8. Stability (Robust to Environmental Noises)
+ 9. Calibration Ease
+ 10. Ease of Manufacturing and Assembly
+ 11. Fluorescence Capability
+ 12. Multiple Use Capability (Can also measure tolerance, perform patient ID)
+ 13. Safety
- 14. Contact with Blood (Instrument contact)

Table 3.3 "Measuring Band" concept selection criteria

Our team's experience from customer interviews and corporate specifications was used to make a list of concept evaluation criteria for the "Measuring Band" sub-system (Table 3.3).

• Corporate specifications require system's measuring precision to be less than 0.0005 inch, and accuracy & repeatability to be greater than 97%.

• Although low cost is important, trade-offs were made given current technological availability. The cost of the "measuring band" system has to be only a fraction of the maximum allowable overall system material cost of $2,000. During evaluation, we analyzed costs for each concept associated with manufacturing, and system interfacing complexities.

• Small size was found to be important to the customers for maintenance ease and countertop space-saving.

• Multiple use capability includes the ability of the "measuring band" system to read patient identification (i.e. bar codes), perform both fluorescence and transmission readings, and also precisely measure the annulus between the float and the tube.

• Another important criterion is safety. The system need to perform its function without compromising user safety.

Evaluated "Measuring Band" Concepts

After an initial Pugh selection process, we attacked the negative aspects of winning concepts and performed more feasibility studies for a second round of concept selection. The "new" winning concepts (Figure 3.7) were evaluated and the results are presented in figure 3.8. Some of the concepts had color analysis and others did not because we believed, at that time, that as long as band lengths were measured, color analysis was not an issue. We found out later that BD's intention of adding more capabilities to the Walkaway system required color analysis.

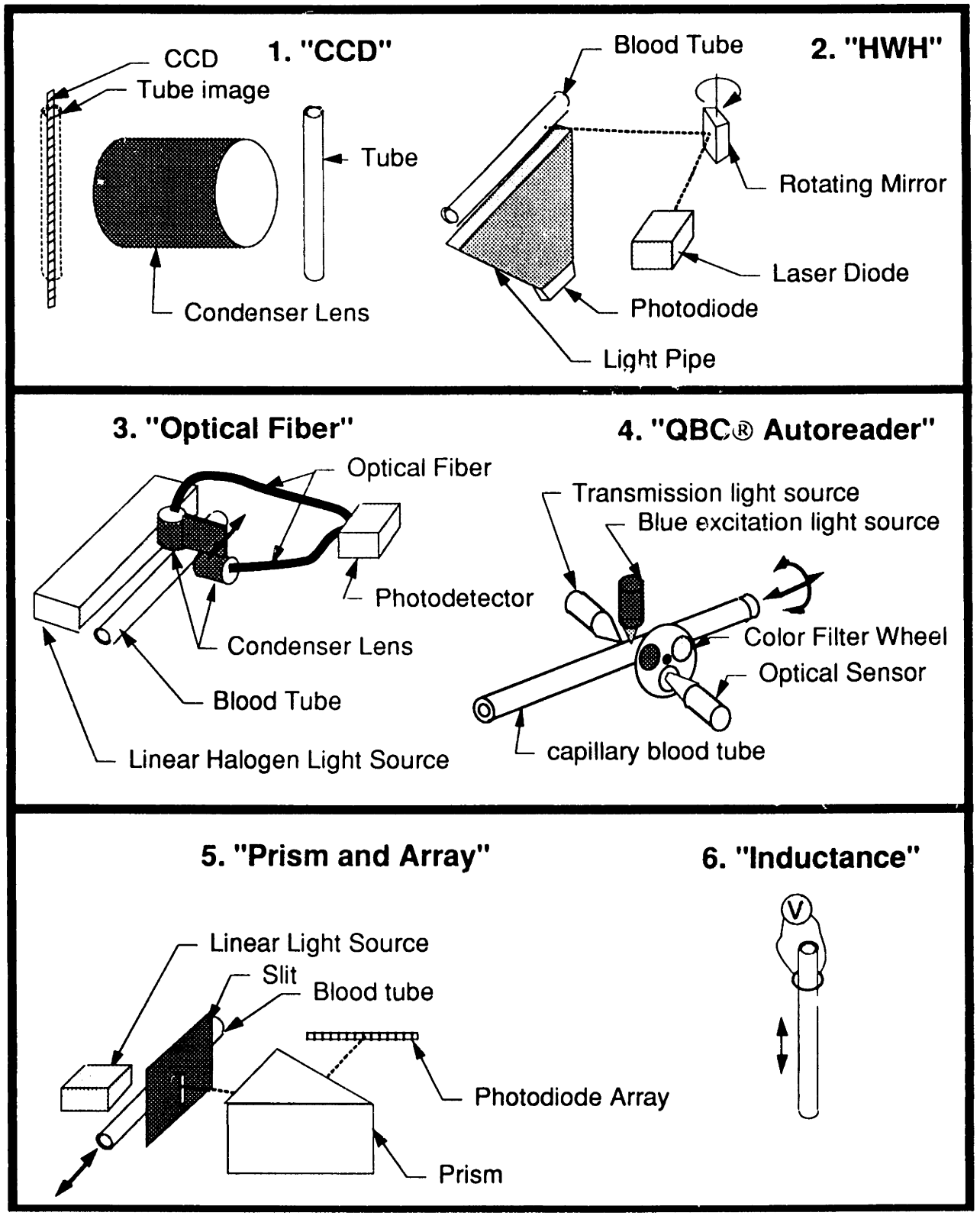
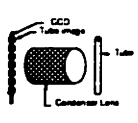
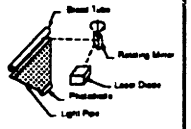
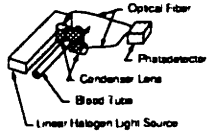
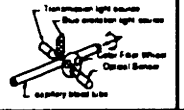


Figure 3.7 "Measuring Band" concepts

"Measuring Band" Concept Selection Design Criteria	1. "CCD" 	2. "HWH" 	3. "Optical Fiber" 	4. "QBC® Autoreader" 	5. "Prism and Array" 	6. "Inductance" 
+ 1. Accuracy	S		S	-	S	S
+ 2. Precision	S		+	-	?	?
+ 3. Repeatability	+		S	-	S	?
- 4. Cost	-		+	S	-	+
+ 5. Reliability (Mean Time Between Failure)	?		S	-	S	+
- 6. Size	S		+	-	S	+
+ 7. Speed (Speed of Taking Measurement)	S		-	-	-	-
+ 8. Stability (Ruggedness & Robust to Environmental Noises)	+		+	S	S	+
+ 9. Calibration Ease	S		S	S	S	S
+ 10. Ease of Manufacturing and Assembly	-		+	-	S	+
+ 11. Fluorescence Capability	+		+	+	+	S
+ 12. Multiple Use Capability (Can also measure tolerance, perform patient ID)	-		-	-	-	-
+ 13. Safety	S		S	S	S	S
- 14. Contact with Blood (Instrument contact)	S		S	S	S	S
SUM	**0**	**0**	**+4**	**-7**	**-2**	**+3**

DATUM

Figure 3.8 "Measuring Band" Pugh chart

1. "CCD"

A CCD and a condensing lens simply take pictures of a tube.

The "CCD" performed well in repeatability because of no moving parts. Moving parts can lead to misalignment and instability.

Score: 0

2. DATUM "HWH"

We chose the "HWH" as the datum because of our familiarity and having the potential to be the best concept. The "HWH" is the most recent BD blood analysis product that can simply and cost-effectively provide a few blood parameters with the use of a laser that scans the axis of a centrifuged blood tube. The light is collected through a light pipe to a single photodiode. The position of the laser point on the tube and light intensity detected by the photodiode are used for measuring blood bands. Based on BD's research and development team, there is hope that this laser technology can be improved to obtain all the necessary blood parameters. (The "HWH" is currently marketed by BD as "Hemascan.")

Score: 0

3. "Optical Fiber"

Two optical fibers and their respective condenser lens scan the tube twice axially for transmission and fluorescence readings. The tube is illuminated with a linear light source. During a scan, a fiber collects the light from the tube and its intensity is measured by a single photodetector. Changes in intensity indicate a change in band.

The "Optical Fiber" was favored in several criteria: potential precision, cost, size, stability, and ease of manufacturing and assembly. We felt that a condenser lens and optical fiber set-up would be inexpensive and yet be able

to provide the necessary precision. Flexible optical fibers might also make assembly easy.

Score: +3

4. "QBC® Autoreader"

This is the current QBC® Autoreader machine. A tube is scanned across a photodetector (see section 1.4 for more details).

This most recent product performed poorly in many criteria. It did not have the required accuracy nor the precision. It had a very slow scan and analysis time of 2 minutes per tube.

Score: -8

5. "Prism and Array"

This concept is based on the ability to differentiate band colors. The tube moves across a small slit and the light beam emanating from the slit will enter a prism, diffract, and position itself on a linear photodiode array. Abrupt changes in light wavelength content signify band boundaries and the light distribution over the photodiode array provides color information.

This concept lost in many categories, because it requires many mechanical components to move the tube across an optical slit. Being similar to the "QBC® Autoreader.," the moving mechanical components add cost and complexity, and decrease machine speed.

Score: -3

6. "Inductance"

A wire loop around the tube moves up and down the tube axially and the inductance change at each band transition is measured and recorded. We expected that varying blood cell densities might give inductance changes.

The "Inductance" concept tied with the optical fiber and photodetector combination. It won in cost, reliability, stability, ease of manufacturing & assembly, and size; it only requires a wire and electronic circuitry. We are still unsure of its accuracy, precision, and repeatability. Moreover, since it is not an optical system, it can't perform fluorescence readings. This major drawback forced us to eliminate this concept.

Score: +3 and 3 unevaluated criteria

"Measuring Band" Concept Selection Conclusion

Two potentially *strong concepts* emerged from the initial Pugh concept selection process: "HWH" and "Optical Fiber". Their strengths were cost, simplicity, and having potential to achieve the necessary precision and accuracy.

The "HWH" concept is dependent on blue laser or blue LED technology for performing fluorescence readings. Unfortunately, these technologies are still in a rudimentary stage of development. The current technological status makes the "HWH" concept impractical for further development at this time, although the next generation of QBC® system might use the "HWH" concept. The "Optical Fiber" concept was determined to be the only practical solution for obtaining blood band color information, we decided to use a rotating holographic diffraction grating and a photodetector. If we had added to the design criteria such as "(+) technology availability" and "(-) need for research," the "Optical Fiber" would have been the clear winner.

While we were trying to determine the feasibility of using a blue laser or a blue LED, we developed a hybrid based on the "HWH" concept. This idea was intended to minimize moving components and dramatically increase scanning speed. It uses a two degree of freedom mirror which directs laser light to 8 different parabolic mirror segments around the circumference of the tube (Figure 3.9). In other words, it is like having eight "HWH" mechanisms around the circumference of the blood tube so that the tube does not have to be rotated eight times. The laser reflects off each parabolic mirror segment radially to the tube and scans along the tube axis. After the mirror completes the scan, it rotates to perform another scan. Unfortunately, this idea still assumes the availability of blue laser or LED but this is certainly a strong concept to be considered for future generation of QBC® systems.

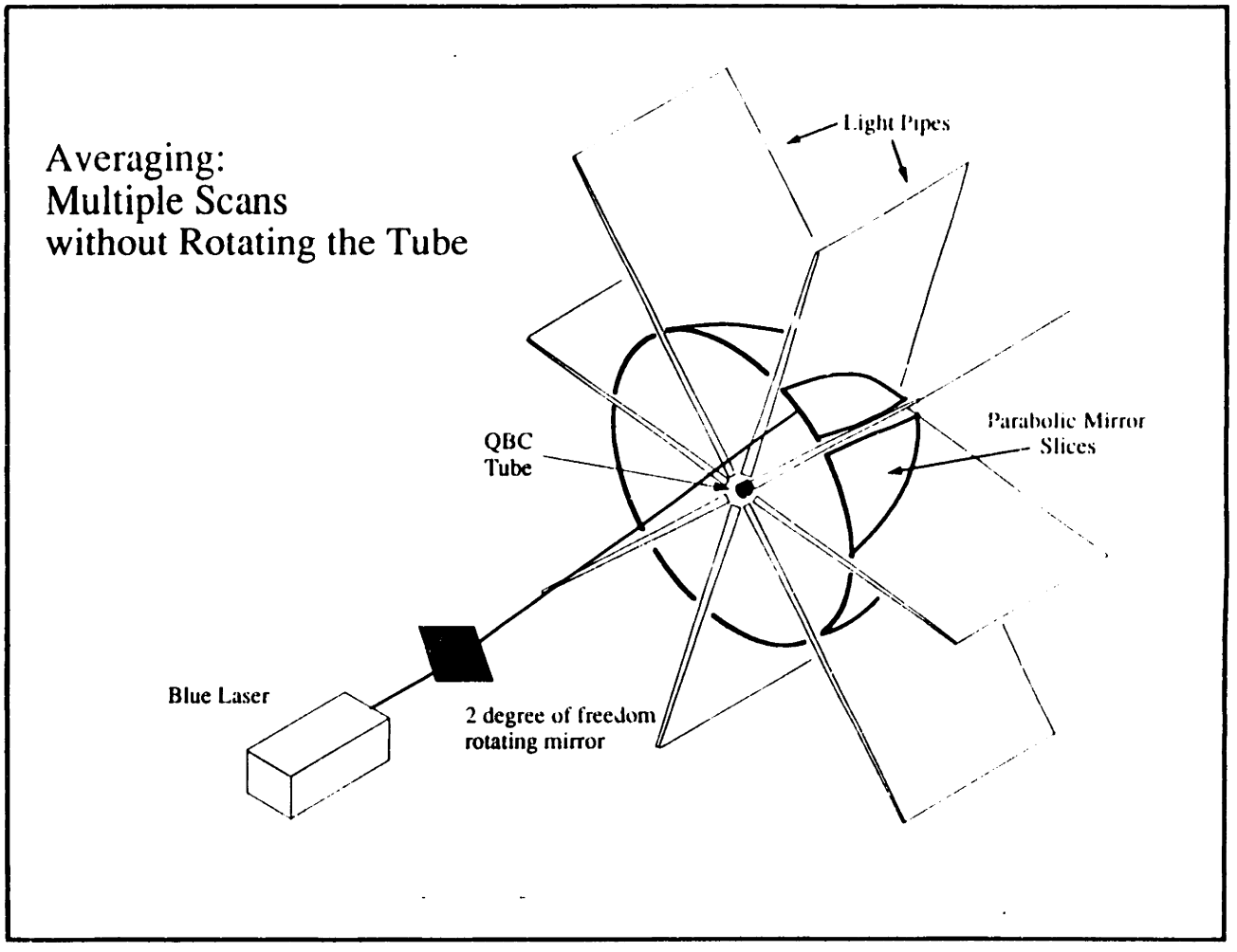


Figure 3.9 "HWH" hybrid optical measuring system[31]

We did not want to focus on just the "Optical Fiber" concept, so we went back to the Pugh chart and decided to perform more detailed feasibility studies on the "CCD" concept, the next "strong" concept. After contacting CCD vendors and learning about its technology, Benjamin Linder determined that a CCD could very well be another feasible solution to measuring bands. A tube's image can be easily focused onto a linear CCD array with a wide-field lens. The tube can be illuminated using a linear light source (Figure 3.10). Blood color information can be obtained with a set of color filters in front of the CCD. In retrospect, our team did not understand the CCD technology nor its availability very well until we performed some extensive vendor research, and so this lack of information about reliability, cost, and manufacturability led us to *believe* that the "CCD" was not a "strong" concept.

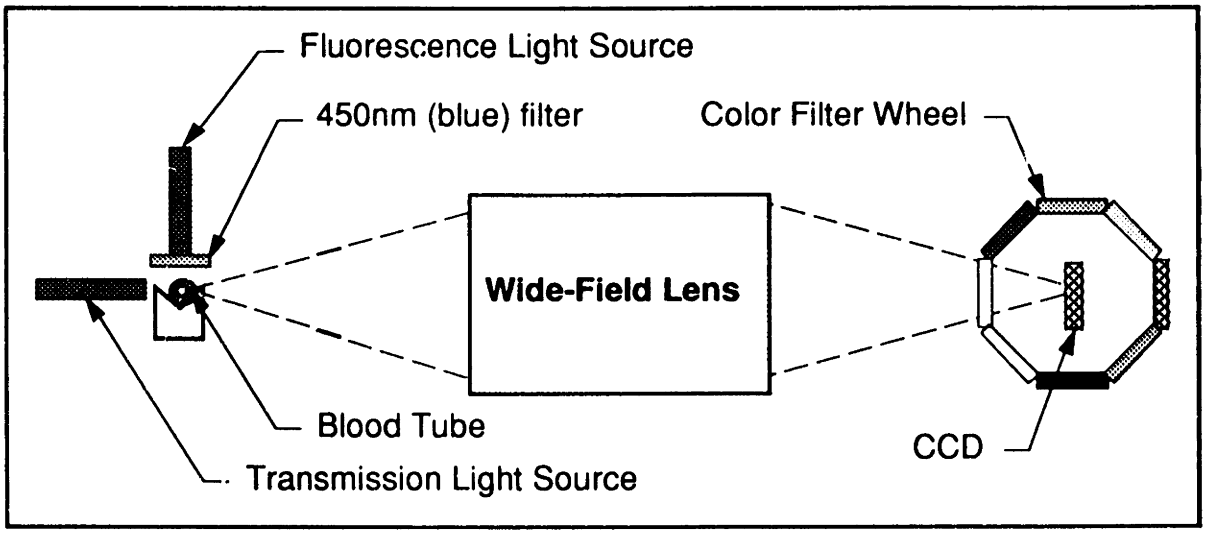


Figure 3.10 "CCD" optical system

At that point in the design process, two concepts had been selected for breadboarding; "Optical Fiber" and "CCD". The "HWH" concept and its hybrid was shelved because of the current unavailability of reliable and cost-effective blue light sources.

3.2.3 "Measuring Float & Tube Annulus"

Knowing the dimension of the annulus between the float and capillary tube is very important for theWalkaway system accuracy. Currently, the manufacturing tolerances for the float and tube (+/- 0.00015) are not tight enough to give the necessary accuracy to compete with the impedance-counting hematology instruments. Thus, BD required that the QBC® Walkaway system deal with this problem to achieve the required accuracy specifications. The design criteria for this system included cost, speed, reliability, user interaction, manufacturing issues, and, of course, accuracy (Table 3.4).

"Measuring Float and Tube Annulus" Concept Selection Design Criteria
+ 1. Accuracy
+ 2. Precision (resolution)
+ 3. Repeatability
+ 4. Ruggedness (sensitivity to environmental noise)
+ 5. Measure with Blood (i.e. Can the annulus measurement be done when blood is in the tube?)
- 6. Cost/sample
- 7. Additional cost to system
+ 8. Reliability
- 9. Size
+ 10. Speed
+ 11. Ease of Maintenance
+ 12. Ease of Calibration
+ 13. Ease of Manufacturing/Assembly
+ 14. Multiple Use Capability (ie/ Could this measurement technique be also used to measure bands? Will this technique measure tolerances on both the tube and the float?)
+ 15. Safety

Table 3.4 "Measuring Float and Tube Annulus" Concept Selection Design Criteria

Evaluated "Measuring Float and Tube Annulus" Concepts

After having understood each design criterion for "Measuring Float & Tube Annulus," our team held several brainstorming sessions and followed up with several concept evaluation and selection sessions. We selected 8 concepts after preliminary feasibility studies and Pugh concept selection. Some of these concepts are shown in figure 3.11 for clarification. The Pugh chart is presented in figure 3.12.

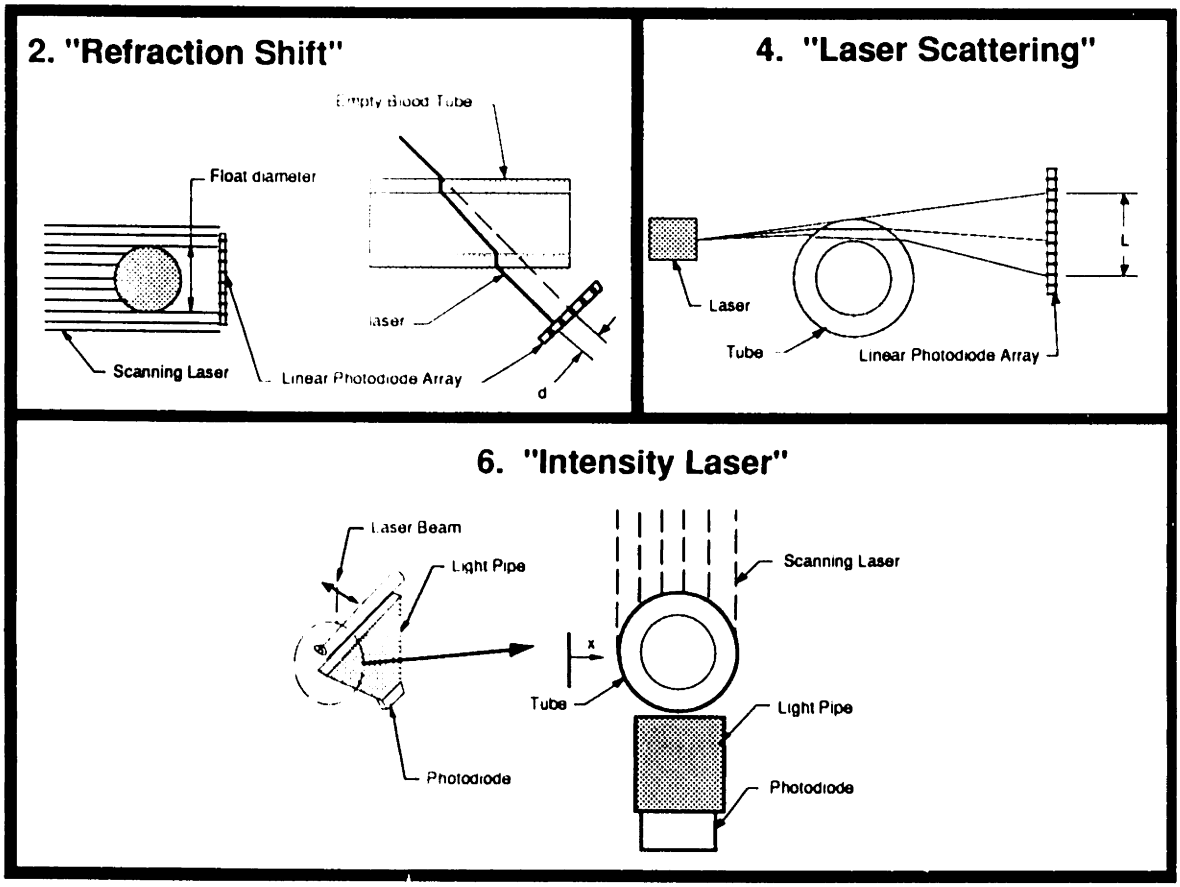


Figure 3.11 "Measuring Float and Tube Annulus" concept drawings

"Measuring Float and Tube Annulus" Concept Selection Design Criteria	"Magic Brew"	"Refraction Shift"	"CCD"	"Laser Scattering"	"Double Tube"	"Intensity Laser"	"Reusable Float"	"Super Floats"
+ 1. Accuracy	DATUM	+	+	+	S	+	S	S
+ 2. Precision (resolution)		-	-	S	S	S	S	S
+ 3. Repeatability		S	S	S	S	S	S	S
+ 4. Ruggedness (sensitivity to environmental noise)		-	-	-	S	-	S	S
+ 5. Measure with Blood (i.e. Can the annulus measurement be done when blood is in the tube?)		-	S	S	S	S	S	S
- 6. Cost/sample		+	+	+	-	+	+	-
- 7. Additional cost to system		-	-	-	S	-	-	S
+ 8. Reliability		S	S	-	S	S	S	S
- 9. Size		-	-	-	S	-	-	S
+ 10. Speed		-	S	S	S	-	S	S
+ 11. Ease of Maintenance		S	S	S	S	S	-	S
+ 12. Ease of Calibration		S	S	+	S	-	S	S
+ 13. Ease of Manufacturing and Assembly		S	+	+	+	+	+	+
+ 14. Multiple Use Capability (ie/ Could this measurement technique be also used to measure bands? Will this technique measure tolerances on both the tube and the float?)		S	S	S	S	S	S	S
+ 15. Safety		S	S	S	-	S	-	S
SUM	0	-2	-1	-1	-1	-1	-2	0

Figure 3.12 "Measuring Float and Tube Annulus" Pugh Chart

1. DATUM: "Magic Brew"

When the tubes are manufactured and reagents are sprayed inside, an additional substance of a precisely known volume is placed inside the tube. This substance has the same specific gravity as the float. Thus, when centrifuged with blood, it becomes a reference band. Measuring the length of this band determines the annulus dimension.

This concept was a clear winner in many categories, including speed, ruggedness and machine cost; there is no need for additional inspection routines in the machine. It was determined to be less desirable in terms of accuracy and cost per test mainly because it requires precision volumetric injection of a substance with the proper specific gravity.

Score: 0

2. "Refraction Shift"

This is a two-step process in which the outer diameter of the float is measured by scanning a laser across the float to measure its diameter; and the tube's inner diameter is measured by shining a laser light beam through the tube at an angle to its axis. The annulus can be found by measuring the distance "d" that the light is offset from its original path and knowing the tube's refractive index..

This concept was one of the few methods that might not require a new manufacturing process for the tube/float assembly. It scored well for its cost per test and ease of manufacturing. It was considered less favorable in ruggedness, speed, and machine cost. In addition, we were unable to estimate its accuracy because we did not have any precision optical measuring equipment to perform the necessary experiments.

Score: -2

3. *"CCD"*

This concept uses a CCD linear array to receive an image of an*empty* tube with float already inserted. By detecting sharp changes in intensity normal to the tube's axis (rather than axially as shown in Figure 3.7), the annulus dimension may potentially be determined.

As with the "refraction shift", this concept scored well for cost per test and ease of manufacturing because it does not require any additional disposables as with the "Magic Brew". It also received favorable scores for its accuracy and multiple use capability. But precision was a very weak area since the annulus width needs to be measured with at least 0.0001 inch precision. CCD pixels are usually greater than 0.0003 inch. A precision 3:1 lens may be used but this significantly adds cost and increases complexity. Furthermore, the concept requires measuring the annulus without blood. This is a disadvantage because an empty tube has to be first inserted into the machine and re-inserted after drawing blood and centrifuging.

Score: -1

4. *"Laser Scattering"*

This is a patented laser light scattering technique currently being developed for the tube manufacturing plant. Refracted laser beams through the tube's cross-section and their positions on the linear photodiode array are used to measure the annulus dimension.

This concept requires a laser and a linear photodiode array which can be costly. Since the same laser can not be used for measuring bands, it adds additional cost and complexity.

Score: -1

5. *"Double tube"*

This concept calls for a tube and float that are twice as long. This concept doubles the length of each band, and thus doubles the accuracy.

This concept scored almost identically to "magic brew" except for a more favorable rating for ease of manufacturing, and a less favorable rating for cost per test and safety (easier to break tube).

Score: -1

6. *"Intensity Laser"*

This concept uses the "HWH" technology (see section 3.2.2) to scan the tube across the diameter of the tube. Sharp changes in intensity during the scan indicate the location of the tube and float edges.

This idea requires measuring the annulus without blood like the "CCD" concept. Precision is limited by the laser beam's diameter and its scanning velocity.

Score: -1

7. *"Reusable float"*

In this concept a high precision float is manufactured. Its dimensions are measured carefully once and stored in the QBC® machine. It is attached to a string and dropped into each tube before centrifuging. After reading, the float is retrieved and automatically cleaned for re-use. This concept scored well for its low cost per test and ease of manufacturing, but performed poorly in cost, ease of maintenance, and safety. Extremely tight manufacturing tolerances on the float, and the need for automatic cleaning and cleaning agents make this system very undesirable. There is also a need for a material whose dimensions that does not change much from wear due to repeated insertions and cleaning.

Score: -2

8. *"Super Floats"*

These floats are highly precise floats manufactured of a material yet to be determined (possibly a ceramic composite). Band measurement accuracy can increase with more precise floats.

This concept scored identically to "magic brew". This idea was unfavorable because extremely tight float tolerances might considerably add to the cost per sample.

Score: 0

"Measuring Float and Tube Annulus" Concept Selection Conclusion

The winning concepts included laser measurement techniques and methods requiring additional manufacturing. Unfortunately, we felt that there were nc apparently strong concepts. The "Magic Brew" and "Super Floats" were the best systems scoring "0"; (i.e. "Magic Brew" was the datum and only "Super Float" did as well).

However, about a month after the presenting three system concepts on May 8, 1992 to BD, the inventors of the QBC® technology developed a patent-pending technique that can effectively measure the annulus between the float and tube without incurring any additional hardware cost to the system when used with an *optical* band measuring method. It uses a float with a tapered section and the fluorescence intensity is measured along this taper to obtain a linear calibration curve in determining the annulus dimension. We intend to integrate this annulus measuring technique with one of the optical band measuring methods.

3.2.4 "Display"

Human interface is characterized by a whole set of attributes which is important to the users. Human interface issues include the way information is shown to the user and how the user interacts with a machine to obtain the information and control its functions. Some of the details of human interface can include the location and size of input buttons, positioning of the display, level of complexity of menu items on the display, and the arrangement and information shown. For example, blood cell counts can be displayed using a pull-down menu command. The CBC can be displayed with bar or pie charts in black & white or in color. Mark Driscoll's thesis contains many variations of display formats that were simulated using the SUPERCARD™ software.[32]

For the function "display", however, we focused on the main hardware features of the QBC® Walkaway system:

- The visual system for displaying the necessary information such as blood analysis results, quality control information, patient identification, calibration data and suggested diagnoses.
- The interior electronics or computer to drive the visual information display
- Input hardware interface to allow the user to select and visualize the desired information

"Display" Concept Selection Design Criteria
- 1. Cost
+ 2. Reliability
+ 3. Screen aesthetics (graphics capability, color, font choice, etc..)
+ 4. Ruggedness to environmental effects such as temperature, blood splashes, humidity, etc...
- 5. Size of display
+ 6. Readability (size of letters, clarity, brightness, etc...)
+ 7. Ease of interaction
+ 8. Ease of maintenance
+ 9. Ease of learning
+ 10. Manufacturability
+ 11. Power Efficiency
+ 12. Customizability (display format, menu format, etc.)

Table 3.5 "Display" Concept Selection Design Criteria

The concepts were evaluated with a set of design criteria shown in Table 3.5. The "display" concept selection criteria included cost, ease of use, versatility, and manufacturability. Ease of use and versatility dealt with:

- ease of learning what the display shows
- readability such as character sizes and their clarity and brightness
- aesthetics such as color, graphics, and font choice
- ease of interacting with the machine to obtain and input the desired information
- versatility to give the user the ability to customize the format of displayed information

Evaluated "Display" Concepts

Refer to the concept drawings (Figure 3.13) and the Pugh chart (Figure 3.14) for the following concept evaluations.

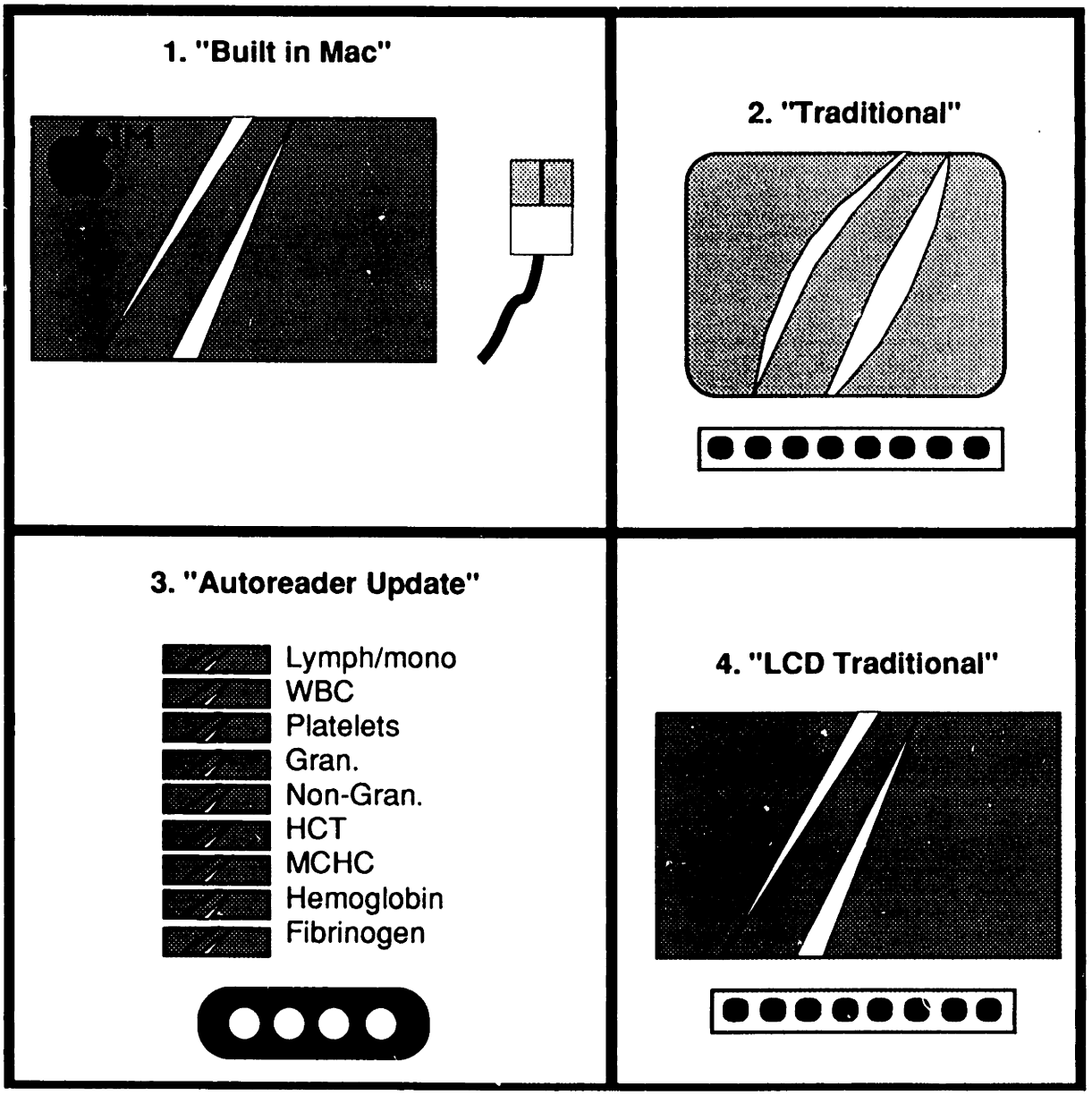


Figure 3.13 "Display" concepts

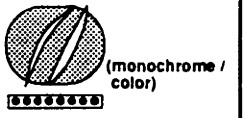
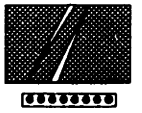
"Display" Concept Selection Design Criteria	1. "Built in Mac" 	2. "Traditional"  (monochrome / color)	3. "Autoreader Update" 	4. "LCD Traditional" 
- 1. Cost		+ / -	+	+
+ 2. Reliability		- / -	+	S
+ 3. Screen aesthetics (eg. graphics, color, font choice)	D	S / +	S	S
+ 4. Ruggedness to environmental effects (temperature, blood splashes, & humidity)	A	+ / +	+	S
- 5. Size of display		- / -	+	S
+ 6. Readability (size of letters, clarity, brightness, etc...)	T	+ / +	+	S
+ 7. Ease of interaction		? / ?	?	?
+ 8. Ease of maintenance	U	- / -	S	S
+ 9. Ease of learning		? / ?	+	?
+ 10. Manufacturability		S / S	+	S
+ 11. Power Efficiency		- / -	S	S
+ 12. Customizability (display format, menu format, etc.)	M	S / S	-	S
SUM		-1 / -2	+3	+1

Figure 3.14 "Display" Pugh chart

1. *DATUM: "Built in Mac"*

This concept has a built-in macintosh or PC. It had a large liquid crystal display (LCD) that can be rotated up, down, left, and right to ease viewing. A track ball or a mouse is used to access virtual controls appearing on the screen in a menu format. This provides the user with a high level of autonomy in running the QBC® machine.

This concept provided the flexibility and the ability to adapt to different users, and allowed for easy software upgrades. Ease of use, ease of learning, style, and aesthetics were also determined to be strong points of this design. However, high costs and possible low reliability (from blood contamination) were among the unfavorable attributes of large LCD screens.

Score: 0

2. *"Traditional"*

This concept was "traditional" in that all controls were in the form of buttons and switches on the front of the machine. It contained a pre-programmed EPROM rather than an entire computer system. Its display was a monochrome or color CRT monitor.

This concept fared as well as the "Built-in Mac" in terms of it's ease of use and aesthetics. We believed the CRT would be more readable than an LCD because the CRT's viewing angle is often limited and changing its viewing angle required manual adjustments. However, maintenance was given a "-" because static charge on a CRT tends to collect dust. In addition, the lack of a full computer inside gave the concept less customizability as did the fixed-function buttons. The monochrome monitor was expected to have better reliability and lower cost.

Score: -1 monochrome, -2 color

3. *"Autoreader Update"*

This concept was simply an updated version of the current QBC® Autoreader display with a few buttons and multiple LCD display windows. It also contained a pre-programmed EPROM rather than an entire computer system.

This concept scored well because of it's simplicity, "winning" in terms of cost, reliability, speed, ruggedness, and manufacturability. However, it lacked the flexibility and adaptability found in the other concepts.

Score: +3

4. *"LCD traditional"* (hybrid of 1 &2)

This concept was identical to the "traditional" except that it uses an LCD screen instead of a CRT.

This hybrid was created to combine the size and maintenance features of the "Built-in Mac" with the cost and reliability features of the "traditional" concept. It was judged to be essentially equal to the "Built-in Mac" in all categories but it was deemed less expensive.

Score: +1

"Display" Concept Selection Conclusion

These evaluations were performed based on our feelings rather than on customer's wants because we have not conducted customer interviews on human interface issues. In any case, we felt that the "Autoreader Update" and the "LCD Traditional" were strong concepts but we can't make these claims yet. However, this evaluation and selection process was certainly helpful for recognizing the issues of human interface and "display" for customer interviews. To select a strong concept, we decided that we need to conduct more market research to determine how much control and autonomy

the users want over the machine and what kind of display they'd like to see. Nanette Palmer and Karon MacLean developed several SUPERCARD™ simulations for the QBC® Walkaway system and have been conducting customer interviews. In addition, we plan to conduct focus groups to determine the relative ease of use and user satisfaction for the various issues relating to patient identification. The results of this market research will be used to develop the final display, display formats, and user input features as well as patient identification methods.

3.3 Three System Concepts

On May 8, 1992, our team presented a status report to Becton Dickinson. The presentation comprised of three system concepts based on the results from the Pugh concept evaluation and selection process. The three systems were arbitrarily developed based on size to best convey the strong ideas. Each of the core engineering graduate students was in charge of presenting the details of one system; I presented the small system, "Fiber Scan", Ben Linder presented the medium system, "Dual Rotor", and Amy Battles presented the large system, "Juke Box".

The "Fiber Scan" and the "Dual Rotor" were the two most feasible concepts. The "Fiber Scan" has one integrated rotor. The "Dual Rotor" system, as the name states, contains two integrated independent centrifuges. The "Juke Box" was presented as a *future* QBC® Walkaway system for large practices and it contains a single motor with multiple centrifuge rotors. This chapter presents an overview for each system; they are summarized in table 3.6. The system features were not meant to be dedicated so they can be interchanged, if desired. For more details, Appendix E contains more diagrams from the presentation.

Specifications	"Fiber Scan"	"Dual Rotor"	"Juke Box"
Size	small	medium	large
Centrifuge	one "World-Class"	two independent centrifuges	one continuous shaft with ~5 clutchable rotors
Tube-Handling	1 whole carousel moves in machine	tubes are read in the carousel/rotor	carousels are transported to clutchable rotor and optical reading station
Scanning Method	lead screw moves a carriage with 2 light source optical fibers and a detection optical fiber	HWH with a rotating mirror can scan two opposing tubes in two carousels in one pass	HWH hybrid: 2 degree of freedom mirror aims lasers and to 8 coaxially located segmented parabolic mirrors. laser is reflected off the parabolic mirror to the tube.
Blue Light Source	halogen light bulb in ellipsoidal mirror with blue filter	pulsed xenon light bulb in ellipsoidal mirror with blue filter	Blue laser diode
Detecting Light Emanating from Tube	optical fiber to photo multiplier tube	a large light pipe to a single channel photodiode	8 axial light pipes to fibers ending in linear array and linear photodiode array scans ends of fibers
Colorometric Analysis	rotating diffraction grating	color filter wheel	transmission diffraction grating to linear photodiode array
Measuring Annulus Between Tube and Float	factory measured and pre-coded on tube	"Magic Brew"	Levine and Wardlaw fluorescence measurement
Tube Indexing Method	round rotating friction drive concentric to carousel	round rotating friction drive concentric to carousel	none needed tube remains stationary
Patient ID	Pre-coded tubes and forms are matched	"Auto ID"	"Bracelet & Tube ID"
Design Champion	Don Lee	Ben Linder	Amy Battles

Table 3.6 System Concept Specification Table

3.3.1 "Fiber Scan" System Concept

"Fiber Scan" system consists of the "Optical Fiber" measuring band concept and a single integrated "World Class" centrifuge (Figure 3.15). The tubes are held in a carousel with an easy to carry "cd-box" like case. The carousel and cd-box unit is inserted into the machine manually (like a compact-disc) and the machine automatically removes the carousel from the case and centrifuges the tubes. After centrifugation, the carousel is transferred to a reading station where each tube is scanned eight times by the fiber optics carriage (Figure 3.16). The annulus between tube and float is found from optically reading a bar code on the tube which contains factory-measured information. Patient identification is performed by matching a pre-coded tube to a pre-coded form. The form is read with a hand-held bar code scanner linked to the machine. After all the analyses have been performed, a the blood tubes can be automatically disposed into a sharps container.

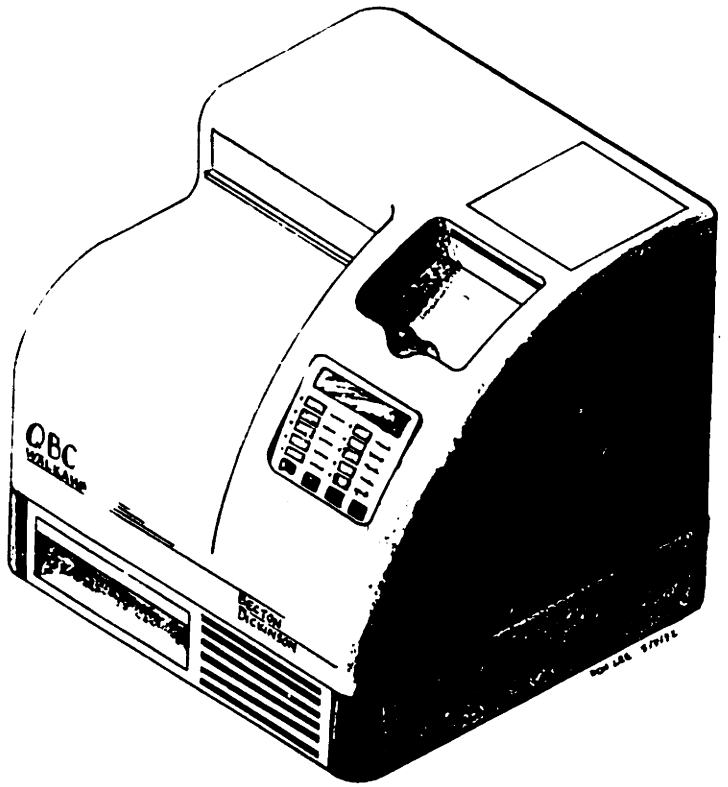


Figure 3.15 "Fiber Scan" system concept

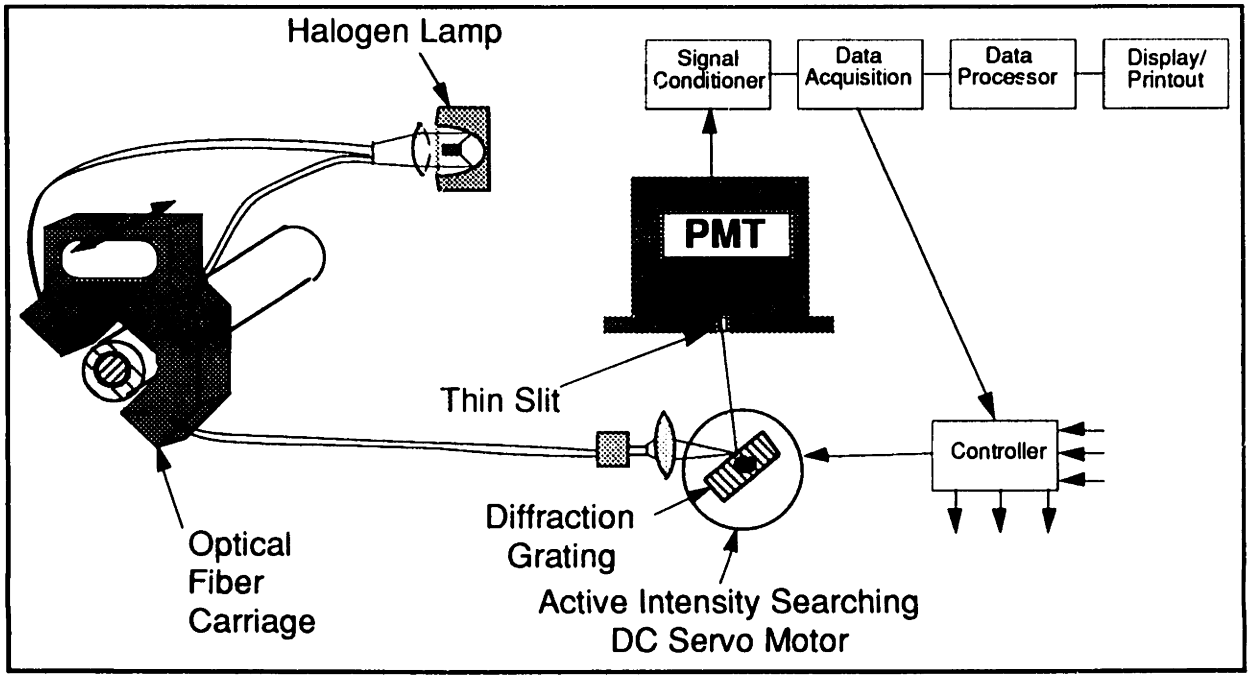


Figure 3.16 "Fiber Scan" optical reading system

The optical reading system is set up to perform both transmission and fluorescence measurements. The light source is a halogen light bulb and two optical fiber bundles are used to illuminate the blood tube for fluorescence readings and for transmission readings. The optical bundle for fluorescence reading contains a blue excitation filter. Only one reading is performed at a time. The transmittance and fluorescence light emanating from the tube is collected by one detector optical fiber. This light is diffracted off a diffraction grating and enters the photo-multiplier tube (PMT) through a thin slit. The diffraction grating separates light into its color components (Figure 3.17) and the slit lets in only a specified wavelength into the PMT. The diffraction grating's angular position gives color information and the PMT senses the light intensity.

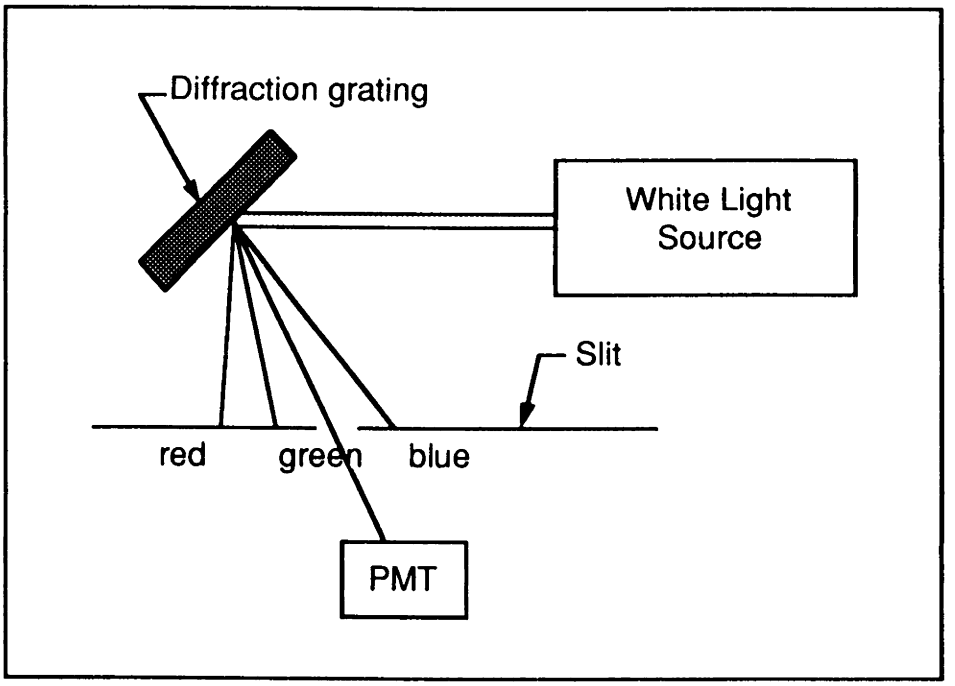


Figure 3.17 Diffraction grating

The diffraction grating is actively controlled by the system computer to determine the wavelength of the light transmitted by the detector fiber. Figure 3.18 shows the logic sequence for band measurement. The position of the diffraction grating providing the strongest light intensity to the PMT directly corresponds to a blood band color. A sudden intensity decrease signifies a new band and the computer actively adjusts the diffraction grating to determine the new wavelength. After this, the optical fiber carriage continues to scan the tube, and the diffraction grating awaits for another band transition. The color searching scheme of the diffraction grating is a speed limiting factor. To increase the scanning speed, the control software can include an adaptive system that can predict the expected bands and re-position the diffraction grating to detect the expected wavelength when a sudden intensity drop is detected. Appendix F contains the diagram of the "Fiber Scan" system.

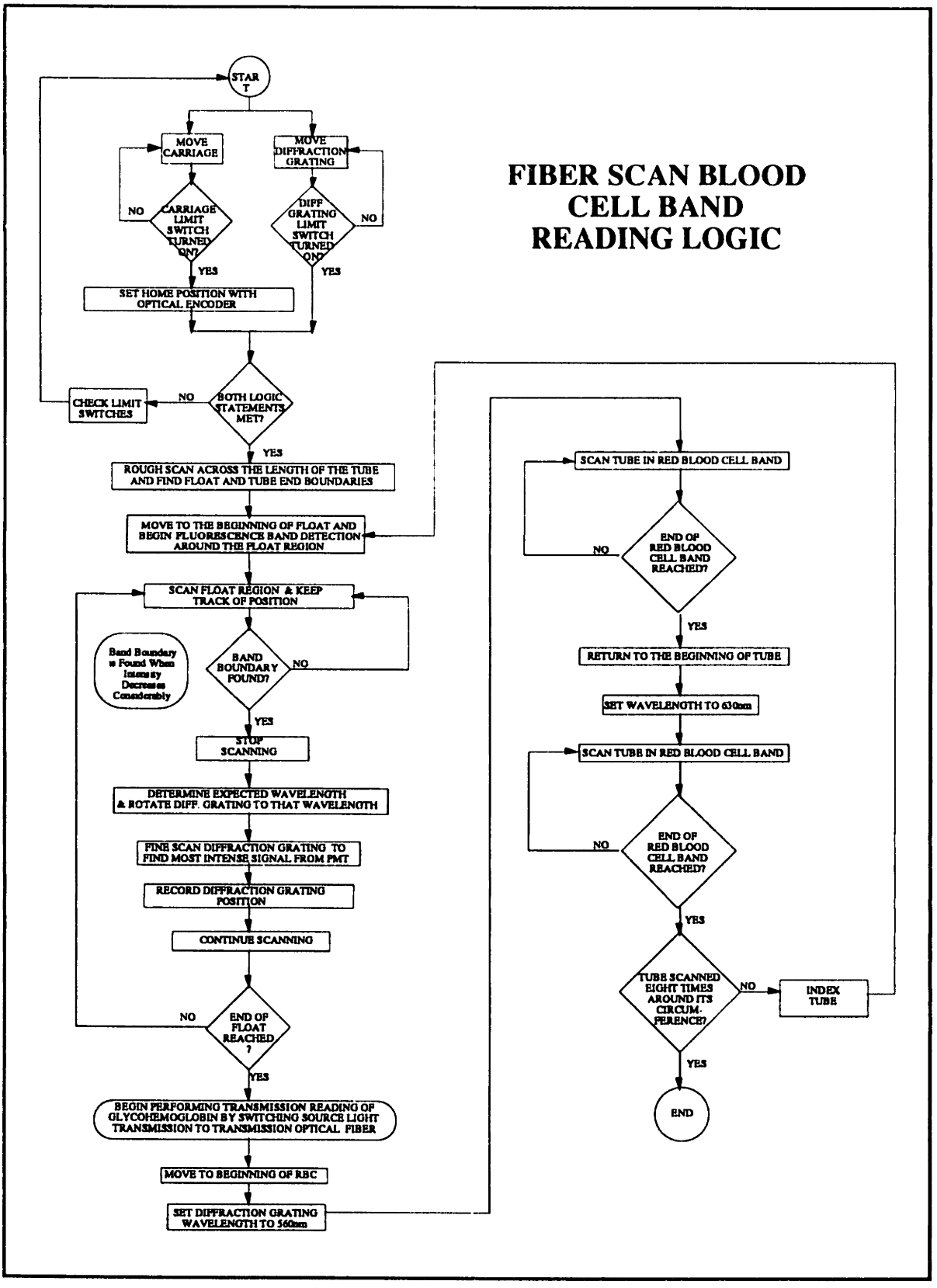


Figure 3.18 "Fiber Scan" Program Logic

3.3.2 "Dual Rotor" System Concept

The "Dual Rotor" system contains two independent centrifuges (Figure 3.19). After centrifuging a carousel, the internal optical system which is based on the "HWH" method reads the tube samples (see Figure 3.7). The fluorescence light source is a concentrated pulsed xenon with a blue filter and it scans axially along the tube via a rotating mirror. This system has a single light pipe that can scan two opposing tubes in the two side-by-side centrifuges in one pass (Figure 3.20). The light diffusing from the blood tube is collected by the light pipe and transmitted through a color filter wheel to a single photodiode for both transmission and fluorescence readings. The tube and float annulus is measured using the "Magic Brew" concept.

Patient identification is performed using the "Auto ID" concept (section 3.2.1). This external automatic identification system receives patient information from the user through a keyboard and transmits to a laboratory information system (LIS). The system then dispenses an encoded tube with patient information. When the tube is analyzed, the bar code is optically read and the patient identification is automatically printed with the results.

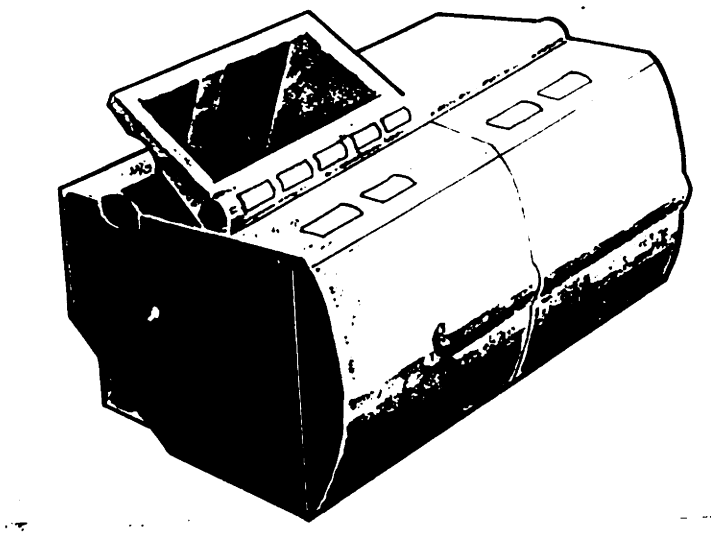


Figure 3.19 "Dual Rotor" system concept[33]

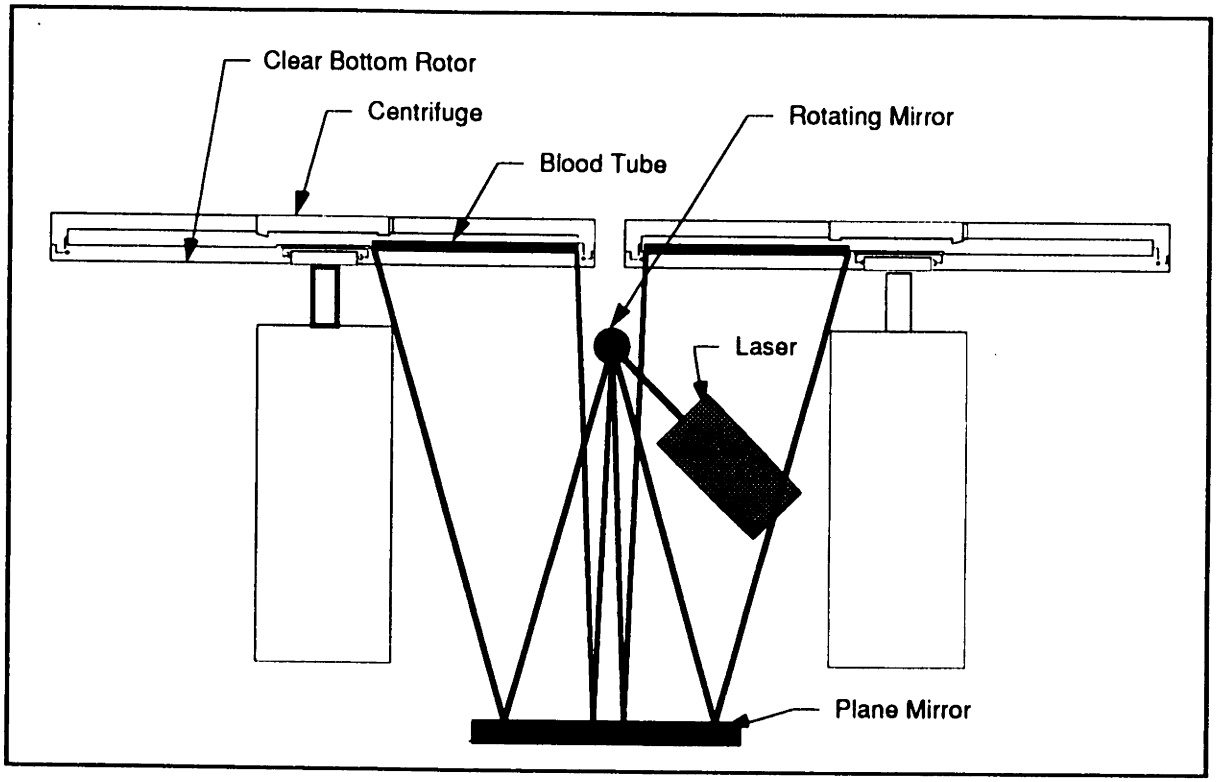


Figure 3.20 "Dual Rotor" optical reading station[34]

3.3.3 "Juke Box" System Concept

"Juke Box" was intended for large physician practices, hospitals, and clinical laboratories that perform large numbers of complete blood counts per day. This system was byfar the most technologically challenging and innovative of the three systems that our team presented. The "Juke Box" has a continuously spinning motor with multiple rotors that can accommodate several carousels (Figure 3.21).[35] The carousels are U-shaped so that they can be inserted onto any empty rotor without interfering with the rotating shaft. The carousels then latch onto a rotor and the electro-rheological fluid in the rotor bearings can be electrically activated to solidify and gradually clutch onto the spinning shaft.[36]

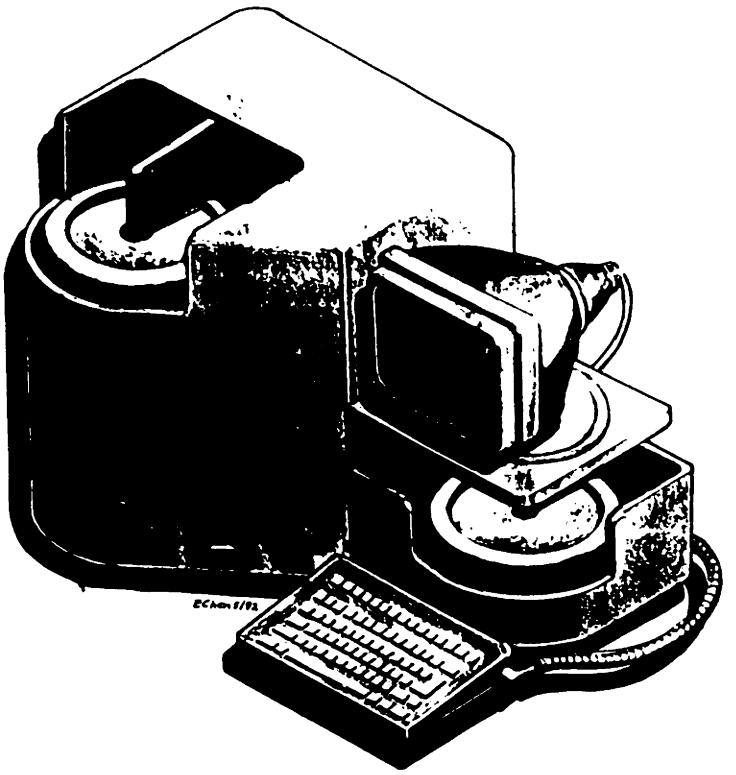


Figure 3.21 "Juke Box" system concept

The optical reading system is the "HWH" hybrid which uses a blue laser diode with a two degree of freedom mirror, eight parabolic mirror segments, eight light pipes, eight optical fibers, and a single photodiode.[37] This concept is like having 8 "HWH" optical reading mechanisms around the circumference of a blood tube and thereby eliminating the need for rotating the tube. The mirror directs the blue laser beam to the parabolic mirrors one at a time to axially scan a tube. The resulting light is collected by a light pipe and it is transmitted through its optical fiber. All the optical fibers end at a single junction where a rotating mask allows the photodiode to detect light from only one optical fiber at a time. The light exits the optical fiber and it is diffracted by a diffraction grating. The location of the diffracted light on the linear photodiode array correlates to its wavelength.

Patient identification for the "Juke Box" system is based on the "Bracelet and Tube ID" concept which assumes that the physician practice

or hospital has a universal patient identification system (section 3.2.1). An LIS linked bar code reader identifies the patient from a bracelet or a card and associates a QBC® tube, with a generic serial bar code, to the patient. The phlebotomist collects the patient's blood and sends it to the laboratory. The blood analyzer performs the necessary functions and the results are sent to the LIS. A doctor can retrieve the results on an office computer.

4. Three Breadboards

Important design requirements of the QBC® Walkaway system are high precision, accuracy and throughput. The technologies for "measuring bands" and "measuring float and tube annulus" are critical to its success. After having performed the sub-system selection process, our product development team developed three breadboards --"CCD Imager", "Fiber Scan", and "Scanning Mirror"-- for evaluating their performance. For measuring the float and tube annulus, we intend to use the Wardlaw and Levine's patent pending technique which can provide the accuracy to meet the corporate requirements. The details and trade-off studies on these optical systems as well as colorimetric analysis methods are presented in this chapter.

4.1 Three Breadboards

Our team and Becton Dickinson selected three optical reading systems for breadboarding: "CCD Imager", "Fiber Scan", and "Scanning Mirror," each based on the "CCD", "Optical Fiber", and a hybrid of "Prism and Array," respectively (see section 3.2.2 for more details). Our team conducted extensive experiments in an effort to determine the best of the three "measuring band" optical solutions. This section will describe the breadboard set-ups, experimental procedures and the selection process.

4.1.1 "Fiber Scan" Breadboard Set-Up

The "Fiber Scan" method is described in section 3.3.1 and its set-up is shown in figure 4.1. This system has two light source optical fiber bundles and one detector optical fiber bundle mounted on a carriage. A set of three 6mm diameter achromat lenses from Rolyn Optics, implanted in the optical fiber carriage, were focused onto the ends of the optical fiber bundles and onto the blood in the tube. (A pair of achromat lenses acted as a condenser lens.) Achromat lenses were used instead of regular convex lenses to minimize optical chromatic aberrations for blood color analysis. A double-ended DC servo motor and leadscrew was used to move the carriage on a precision linear guide. The carriage was connected to the leadscrew nut with a flexural coupling (a leaf spring).[38] The flexural coupling allowed for vertical and lateral errors of the leadscrew's nut motions but maintained the axial stiffness necessary to precisely move the carriage. A Lucas/Ledex Datametrics optical encoder (model #S-10014-1200) was connected to the motor to detect the carriage position. A centrifuged tube was placed on a precisely mounted v-grooved tube holder. The detector fiber transmitted the collected light from the blood tube into an Optometrics monochromator (model #SDMC1-03) which allowed only a specific wavelength to enter an HC120 series Hamamatsu photo-multiplier tube (PMT). A wavelength dial on the monochromator was used to manually select the output wavelength of the light going into the PMT.

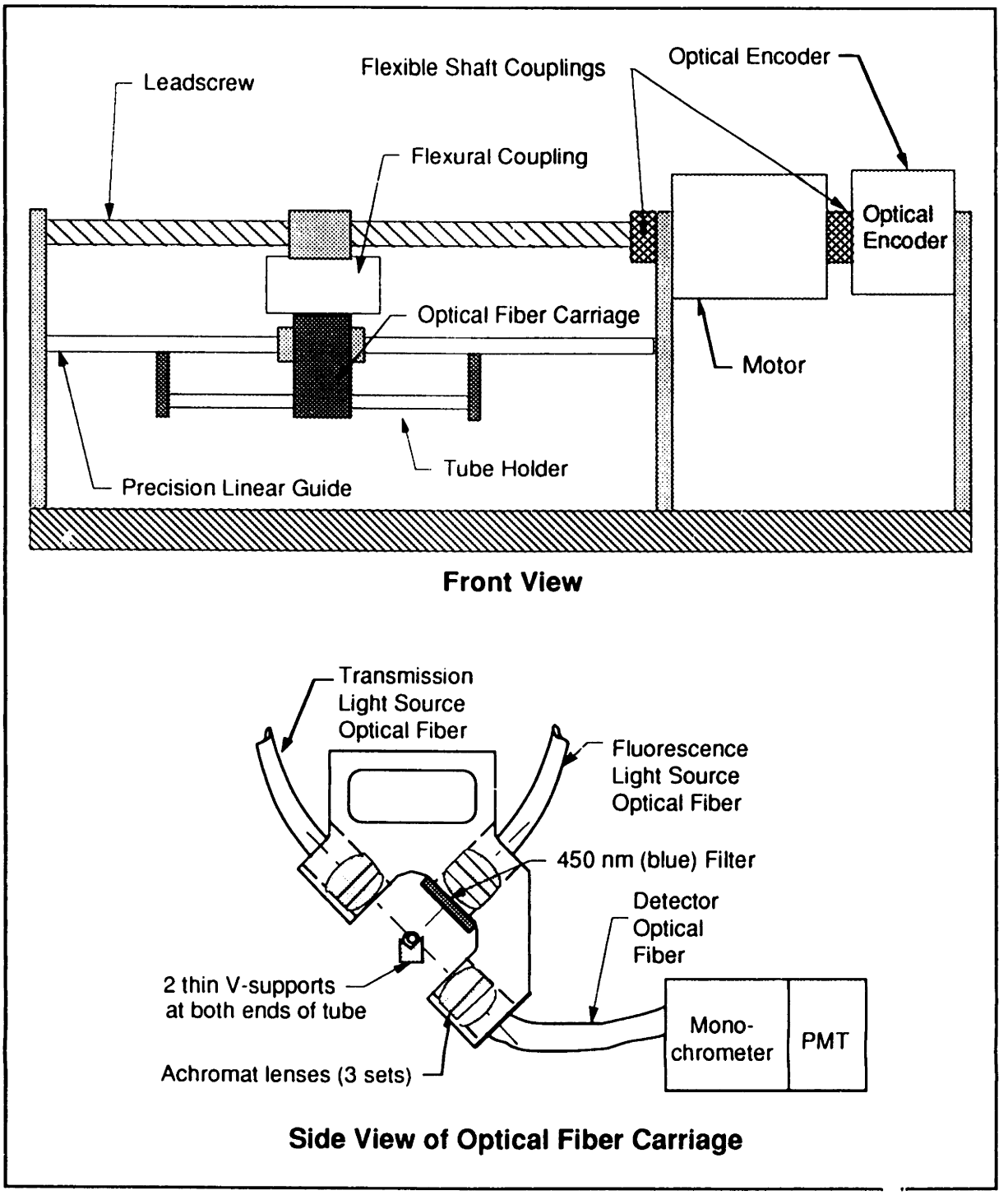


Figure 4.1 "Fiber Scan" experimental set-up

4.1.2 "CCD Imager" Breadboard Set-Up

The "CCD Imager" based on the "CCD" concept, simply took a picture of a centrifuged blood tube. Figure 4.2 shows this system's breadboard. The blood cell color information was intially set up to use color filters but later switched to use a rotating diffraction grating after conducting a trade-off study (see section 4.2.3). Two Cuda circular-to-linear optical fiber bundles (circular end's fiber bundle diameter of 0.125 inch) were connected to a light source to transmit the light to the tube for transmission and fluorescence readings. A JML wide-field lens was used to focus the tube's full image onto a Texas Instrument TC106-1 2591x1 CCD linear array. This CCD was long enough to be able to image the float region. The CCD's exposure time was set at 16ms and 200ms for transmission and fluorescence readings, respectively. The low intensity from fluorescence required a longer CCD exposure time. An Optometrics holographic diffraction grating model 03-2182 was placed between the JML lens and the CCD. It was used to diffract the light from the illuminated tube to allow only a specific range of wavelengths to focus onto the CCD for blood band color analyses. The diffraction grating can be automatically positioned with a 0.45 degree per step Oriental Motors PX243M stepper motor to obtain approximately 10nm color reading precision.

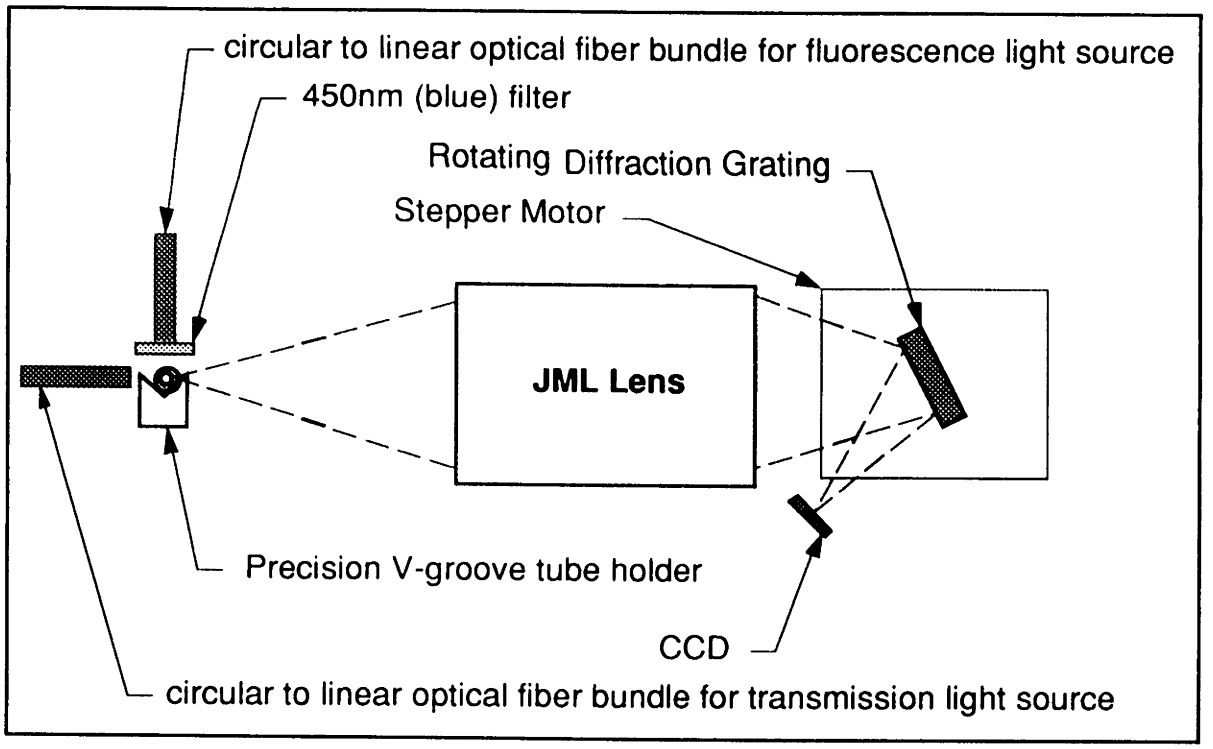


Figure 4.2 "CCD Imager" experimental set-up

4.1.3 "Scanning Mirror" Breadboard Set-Up

The "Scanning Mirror" breadboard was developed based on a hybrid of the "Prism and Array" concept (Figure 4.3). A centrifuged blood tube's image is scanned across a precision micro-hole (12.5 μm diameter) with a continuously scanning mirror driven by a General Scanning galvonometer. The light from the micro-hole was diffracted off a concave diffraction grating which focused it onto a Texas Instrument TC106-1 2591x1 CCD linear array. Color information was found by determining the location of an intense reading detected along the CCD. The galvonometer's speed was set so that a 0.0005 inch section of the tube was illuminated through the micro-hole for the exposure time duration. Hence, the scanning error and the micro-hole size defined this optical system's precision.

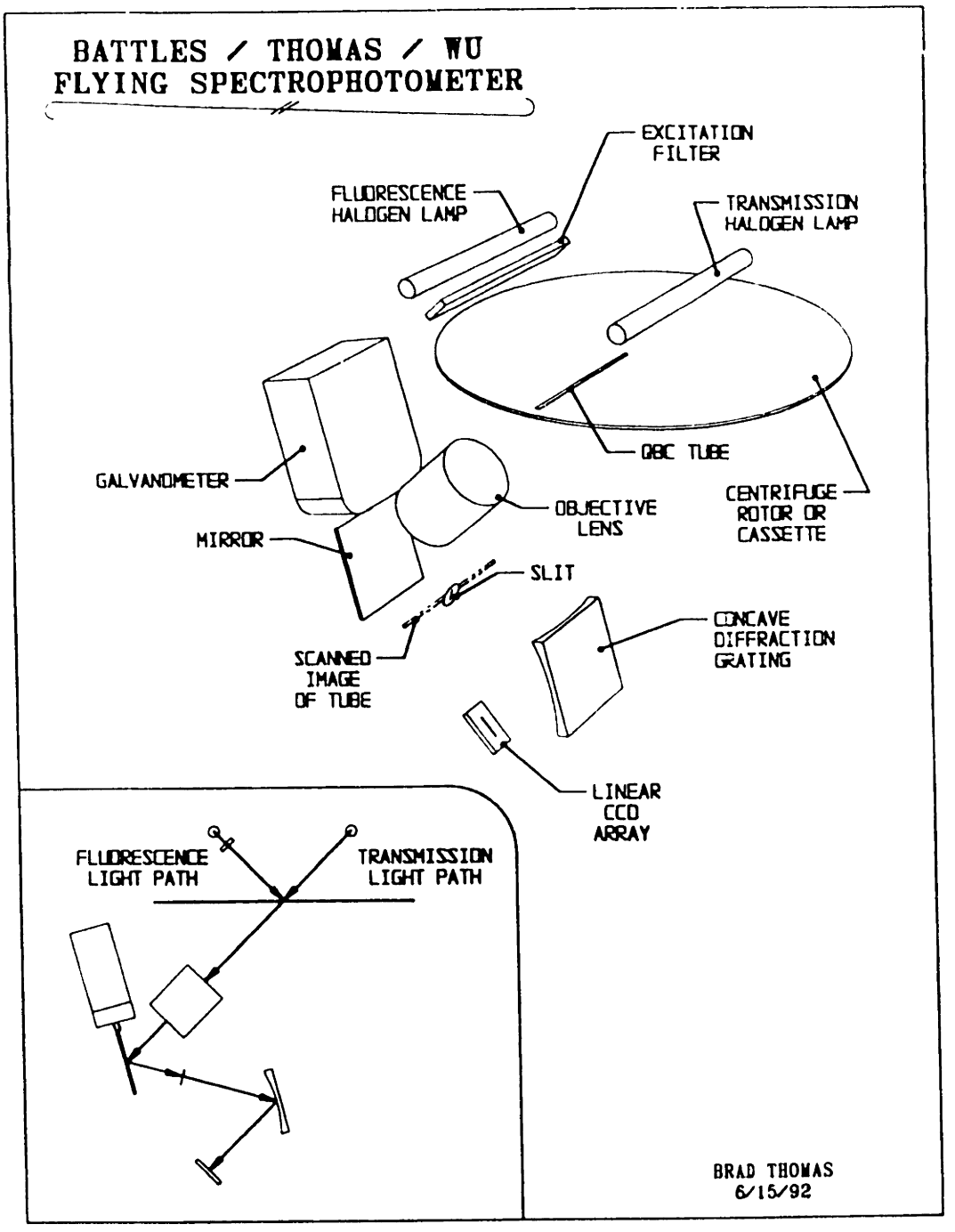


Figure 4.3 "Scanning Mirror" Breadboard Set-Up[39]

4.2 Breadboard selection for final system

After a couple months of setting-up and experimenting with the breadboards, we realized that continuing the development of the "Fiber Scan" and "Scanning Mirror" breadboards was impractical, based on cost and performance issues. A trade-off study of the optical systems was presented to the team. The details of this memo are presented in the following section. After several team discussions, the team and BD reached an agreement to concentrate our efforts on the "CCD Imager" -- the most promising optical system.

4.2.1 Optical BreadboardTrade-off Study

Various issues including cost, performance, and reliability were considered for the breadboard trade-off study. The selection criteria were as follows:

- Material Cost
- Cost and Ease of Manufacturability & Assembly (alignment, number of parts, human interface)
- Precision
- Accuracy
- Repeatability
- Reliability
- Scanning Speed
- Amount of Collected Data and Total Analysis Time

4.2.1.1 Material Cost

For each breadboard, only parts *unique* to the system were considered for cost analysis. Prices were based vendor estimates and BD in quantities above 1000.

"Fiber Scan"

Qty.	Part Description	Approx. Cost ($)
2	optical fibers	30
1	scanning monochromator & controller	400
1	precision rail and optical fiber carriage	100
1	optical encoder (200 counts/rev)	50
1	leadscrew and anti-backlash nut	60
1	photo-multiplier tube	200
1	drive motor & controller	50
1	elliptical reflector & halogen Light bulb	40
2	achromat condenser lenses	30
1	precision mounts	100
2	flexible couplings	20
2	bearings	1
2	limit switches	1
1	flexure	1
	Total Cost:	**$1,073**

"CCD Imager"

Qty.	Part Description	Approx. Cost ($)
1	Kodak linear CCD: 5,000 -10.7μm pixels with 7μm pixel with drive board	200
1	JML Wide-field Lens	100
2	linear optical fiber arrays	70
1	elliptical reflector & Halogen Light bulb	40
1	1" long diffraction grating	30
1	grating stepper drive motor & controller	60
1	precision mounts	50
	Total Cost:	**$550**

"Scanning Mirror"

Qty.	Part Description	Approx. Cost ($)
1	linear CCD 100 Pixels with Drive Board	50
1	JML Wide-field lens	100
1	precision Galvonometer and Controller	150
1	precision micro hole/slit	10
2	linear optical fiber arrays	70
1	elliptical reflector & halogen light bulb	40
1	concave diffraction grating	40
1	precision mounts	200
	Total Cost:	**$660**

The material cost analysis showed that the "CCD Imager" was the least expensive at $550 and the "Fiber Scan" and "Scanning Mirror" costing approximately $1100 and $660, respectively.

4.2.1.2 Cost and Ease of Manufacturability and Assembly Analysis

Each criterion in this analysis was weighed (in parenthesis under each criterion) between 1 and 10 (Table 4.1) based on what I thought were their relative importance. Each breadboard was then ranked against the others between 1 and 10 (in boldface). After evaluation, the criterion weights and breadboard ranks were multiplied for a matrix element score. For example, "number of precision mounts" received a weight of 8 as compared to other criteria. The "Scanning Mirror" received a score of 3 because it required more precision mounts than the other breadboards. For the "number of precision mounts" criterion, the "Scanning Mirror" system got a total score of 24. The matrix element scores for each breadboard were summed and the breadboard with the highest overall score was "declared the winner".

10 - Best
5 - Good
1 - Worst

Criteria	Fiberscan	CCD Imager	Scanning Mirror
number of precision mounts (8)	1x8=8	10x8=80	3x8=24
number of parts to mount (8)	1x8=8	10x8=80	4x8=32
Ease of mounting parts (7)	2x7=14	10x7=70	3x7=21
Ease of Wiring (2)	1x2=2	10x2=20	10x2=20
number and Ease of electronics calibration & setup (8)	6x8=48	8x8=64	6x8=48
approximate amount of space for mounting parts (5)	3x5=15	10x5=50	5x5=25
TOTAL	*95*	***364***	*170*

Table 4.1 Optical system breadboard system analysis

The "CCD Imager" performed the best with an overall score of 364. "Fiber Scan" and "Scanning Mirror" trailed with 95 and 170. The "CCD Imager" is simple with only 5 major parts: CCD, tube holder, lens, diffraction grating and stepper motor. "Fiber Scan," interestingly, turned out to be the most complex system. During concept evaluation, the "Optical Fiber" concept's merits were its simplicity and cost-effectiveness. "Fiber Scan" had many supporting components which were overlooked. "CCD Imager's" simplicity and small size easily surpassed the other breadboards. The team was confident of this analysis.

4.2.1.3 Speed & Memory Requirement Analysis

The optical reading, analysis, and tube handling time for 20 centrifuged blood tube samples cannot exceed 5 minutes according to BD corporate specifications. This translates to about a 15 second average CBC time per tube excluding centrifuge time. An analysis was performed to determine a system that could best meet this requirement (Table 4.2).

Criteria	Fiberscan	CCD Imager	Scanning Mirror
Total scan time per tube length	2 seconds for moving along the tube axis and ~3 seconds to determine band colors for a total of **10 seconds** for both transmission and fluorescence	200 ms x number of scans for color or transmission. If 3 scans then **0.6 seconds**	assume 200 ms exposure time at every .0005 inch increment for a total of **1200 seconds** over the entire 3 inch tube
Amount of data to be analyzed per one scan	2000 points (float area) x 5 bytes per point x 2 + 1 kbyte of color info= **21Kb**	6000 pixels x 5 bytes per pixel X 6 = **180Kb**	100 pixel X 5bytes per pixel X 6000 points on tube X 2 for transmission and fluorescence = **6 Mb** (All this data need to be kept to accrue intensity readings)
Analysis time per tube (arb. scale) order of magnitude estimation	**1** real time color identification for the 2 scans reduces analysis time	**10** 3 different scans need to be analyzed	**100** A lot of data to shuffle around for filtering, band identification, and color information
Total Scan time for 1 rough scan (fiberscan only) and 8 fine scans around float area	**~30 seconds** per tube	**~10 seconds** per tube	**~9600 seconds** = 160 minutes per tube
Approximate scan and analyses time per tube	**31 seconds**	**<15 seconds**	**> 9600 seconds**
Total data storage capacity needed (RAM) including memory needed for data analyses	**<1 Mb**	**<1 Mb**	**~10 Mb**

Table 4.2 Optical system breadboard speed and memory requirement analysis

Conservative estimates on reading and analysis speed based on performance limitations and memory requirements for each system were presented. The speed limiters for the "Fiber Scan", "CCD Imager" and "Scanning Mirror" were the frequency response of the PMT (~10Khz), CCD exposure time, and method & amount of data collection, respectively.

The anslysis shows that the "CCD Imager" was most capable of meeting the 15 second corporate specification. The "Fiber Scan" came in second with 31 seconds and the "Scanning Mirror" came in a distant last with over 9,000 seconds. Both the "CCD Imager" and "Fiber Scan" required less than 1 megabyte of memory (RAM) for data collection and analysis, whereas the "Scanning Mirror" required about 10 megabytes of memory. Providing information for the entire color spectrum with a 200 ms CCD exposure time for every 0.0005 inch tube increment dramatically increased the "Scanning Mirror" system's memory requirements and limited its speed.

Once again, the "CCD Imager" was the clear winner with its potential capability to perform a complete blood count in less than 15 seconds.

4.2.1.4 Precision, Accuracy, Repeatability, and Reliability Analysis

The optical system must be capable of providing a 0.0005 inch measurement precision. The accuracy might not be an issue if an optical system had excellent repeatability. A highly repeatable system can be mapped and linearized to achieve the necessary accuracy. The systems' optical precision, accuracy and repeatability are addressed in table 4.3.

Criteria	Fiberscan	CCD Imager	Scanning Mirror
Precision	approx .0005", determined by the diameter of the detector fiber	approx .0005", determined by the size of the CCD pixel and the magnification of the JML lens	potentially <.0005", determined by the size of the slit/hole and its mounting position.
Accuracy and Repeatability (which are affected by variability of measuring parameters)	1. Limited by the ability to filter the tremendous amount of noise generated by the PMT. 2. Very precise alignment of the linear guide and carriage to the capillary tube will be needed. There are too many critical alignment issues because of a large number of parts that need precision.	1. Very high accuracy can be achieved once the JML lens' error has been calibrated. 2. The CCD provides very clean signals after eliminating CCD's offset errors. 3. Alignment is very easy. Only the tube holder and CCD need to be properly aligned. Even small angular misalignments will only cause cosine errors. Also, since the JML lens has a rather long focal length, the axial positioning of the tube holder and the CCD would not affect accuracy significantly.	1. Limited by the velocity error of the galvonometer (This problem can't be solved except by very expensive means of control.) 2. A super precise mirror or calibration will be needed. 3. Galvonometer bearings can affect repeatability. 4. Highly precise mounting of the micro slit or hole will be important to achieve high accuracy for the given precision of the slit.
Reliability(arb. units with higher the better)	1 Too many moving parts and necessary alignment	10 Just 1 moving part-- the diffraction grating stepper motor	5 Many parts that need precision mounting increases the chance of getting misaligned

Table 4.3 Optical system breadboard measurement capability analysis

All the systems were potentially capable of providing the necessary precision. However, "Fiber Scan" and "Scanning Mirror" systems exhibited poor accuracy and repeatability.

The "Fiber Scan" required many precision components and a blood tube had to be properly aligned in 6 degrees of freedom. These alignments increase manufacturing and assembly costs as well as increasing the likelihood of becoming misaligned. Moreover, the the achromat lenses had to be focused onto the tubes and onto the optical fibers ends. The need for many precision alignments made the "Fiber Scan" optical system undesirable.

The "Scanning Mirror" lacked a very steady velocity from the galvanometer. Even more expensive galvonometers costing over $1,000 was unable to provide the necessary performance. However, adding a high resolution rotary optical encoder to an inexpensive galvonometer might help, but this additional unit will increase cost and complexity. Furthermore, it was found that precise mounting of the lens, micro-hole, mirror, and concave diffraction grating was essential to focus the tube's image and eliminating unwanted light diffractions. Obtaining the necessary performance from this optical system would be costly and seemingly difficult.

The "CCD Imager" provided crisp signals (0.0005 inch resolution) of a blood tube with very few components. The only *unique* precision mount needed is for the rotating diffraction grating. The "CCD Imager's" simplicity and less precise requirements showed more promise so again, the "CCD Imager" was the clear winner.

4.2.1.5 Breadboard Analysis Conclusion

After having performed all the analyses on the major issues-- cost, manufacturability, assembly, accuracy & repeatability, precision, reliability, scanning speed, analysis time, and necessary random access memory (RAM) -- the "CCD Imager" was determined to be the most promising optical reading system. The "CCD Imager" performed well in cost, ease of manufacturing and assembly, speed, and memory requirement. The "Fiberscan" performed poorly in almost all the categories mainly because of the large number of parts which, unexpectedly, added a lot of complexity and cost. The "Scanning Mirror's" major drawback was the unreasonable scan and analysis time of 4 hours for a single tube. The scanning mirror system inherently takes a long time because it collects color information at every 0.0005 inch increment over the full 3" tube length. Accuracy and repeatability were other areas of concern with this optical system. After evaluating all the designs carefully with the team, an agreement was reached to allocate all our effort on the "CCD Imager".

We learned from our experience with these breadboards. It was quite surprising to find out that the "CCD Imager" was the strongest optical reading system. A more careful process of designing and evaluating the breadboards, before developing them, might have made us realize the superior breadboard. Despite this issue, we were enthusiastic with the success of the "CCD Imager" in measuring bands.

4.2.2 Outputs from the "CCD Imager"

The team performed various preliminary experiments to observe the buffy coat, calibration tube, and high density bar codes with the "CCD Imager" system to evaluate its performance. The Texas Instrument CCD was long enough to image only the length (about 1 inch) of the float region but the prototype will contain a CCD that can image the entire length of a blood capillary tube. The electronics to drive the CCD were developed by Ben Linder, Laura Edwards, and Dave Otten. We used the DAPL data acquisition card and software to process the CCD data. Since Laura was in charge of the "CCD Imager", she developed the data acquisition software and electronics. The other team members helped her to perform the experiments. Some of the results from these experiments are presented in the following sections.

We determined that the optimum light intensity for both fluorescent and transmission readings, given the dynamic range of our CCD, came from a 150 Watt "light box" and Cuda circular-to-linear optical fiber bundles. The light box contained a 150 Watt halogen light bulb that focused the light into the circular end of the optical fiber and the linear end illuminated the float region of the blood tube. The filtered blue excitation light sufficiently fluoresced the blood tube for the CCD to detect. And finally, the CCD was proven to be capable of providing 0.0005 inch resolution when a 0.0005 inch Ronchi grating (a template with thin lines spaced 0.0005 inch apart) was imaged.

4.2.2.1 "CCD Imager" Experiments

The collected CCD data were processed through a Gaussian filter in our data acquisition software DAPL to eliminate any noise. The Gaussian filter that we used was a "sliding-window" calculation.

Window position (i)	1	2	3	4	5	6	7	8	9	10	11	12	13
Weight (w)	1	3	5	7	9	13	15	13	9	7	5	3	1
Data (d)	d_1	d_2	d_3	d_4	d_5	d_6	d_7	d_8	d_9	d_{10}	d_{11}	d_{12}	d_{13}

Each datum d_i, corresponding to a CCD pixel, is multiplied by the corresponding mask weight values w_i, where i is the window position. The weighted data are summed and divided by the sum of the weights to obtain the filtered result G_j which corresponds to the unfiltered center datum, d_7:

$$G_j = \frac{\sum_{i=1}^{13} d_i w_i}{\sum_{i=1}^{13} w_i}.$$

This Gaussian filter algorithm was incorporated into the data processing software using the DAPL data acquisition processing language. With this software, the following experiments were performed[40]:

- Transmission reading of black and white calibration tube
- Fluorescence reading of a green striped fluorescent calibration tube
- Transmission readings of a buffy coat
- Red and green fluorescence buffy coat readings
- Transmission reading of a high density bar code placed over the plasma region.
- Repeatability test with ten readings of same blood tube

Transmission Reading of Black and White Calibration Tube

The black and white calibration tube is used in the current QBC® systems. It contains alternating bands of precise black and white cylindrical plastic that the QBC® machines read for calibration. We imaged this

calibration tube on the CCD with transmission light. The CCD exposure time was set to 16 milliseconds to capture the image. The intensity vs. tube position is shown in figure 4.4. The high and low intensity profiles indicate black and white bands. The sharp and distinct boundaries showed that the tube image was focused on the CCD.

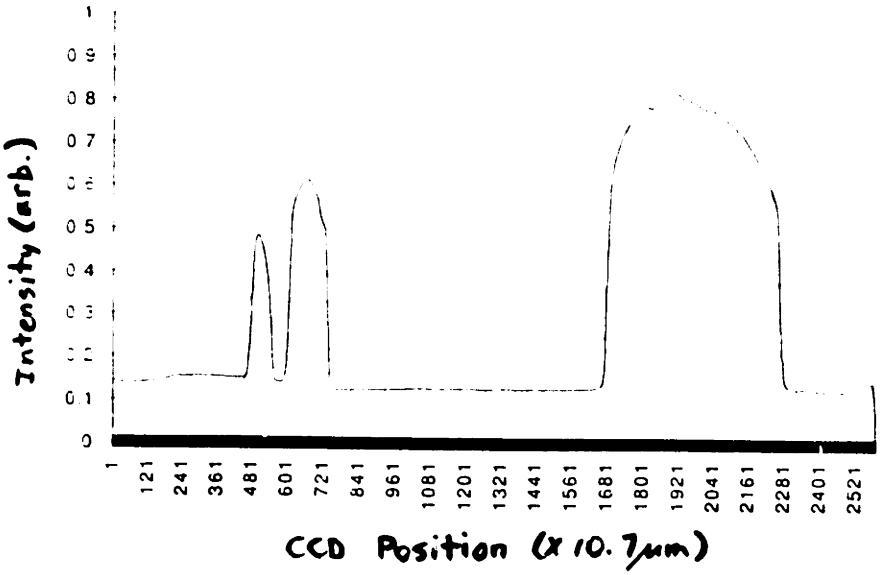


Figure 4.4 Transmission image of black and white calibration tube

Fluorescence reading of a green striped fluorescent calibration tube

A calibration tube with thin fluorescent green stripes spaced approximately 1/4 inch apart was used to check the CCD's fluorscent light detection capability. The tube was excited with 450nm (blue) light which made the stripes fluoresce green. The diffraction grating was positioned to diffract the green light to the CCD. The tube was imaged onto the CCD and the resulting data showed sharp signals at approximately 1/4 inch apart (Figure 4.5). The CCD's exposure time of 200 milliseconds was found to give the best fluorescence intensity measurements. This experiment proved that the CCD was capable of detecting very low intensity fluorescence from a QBC® blood tube.

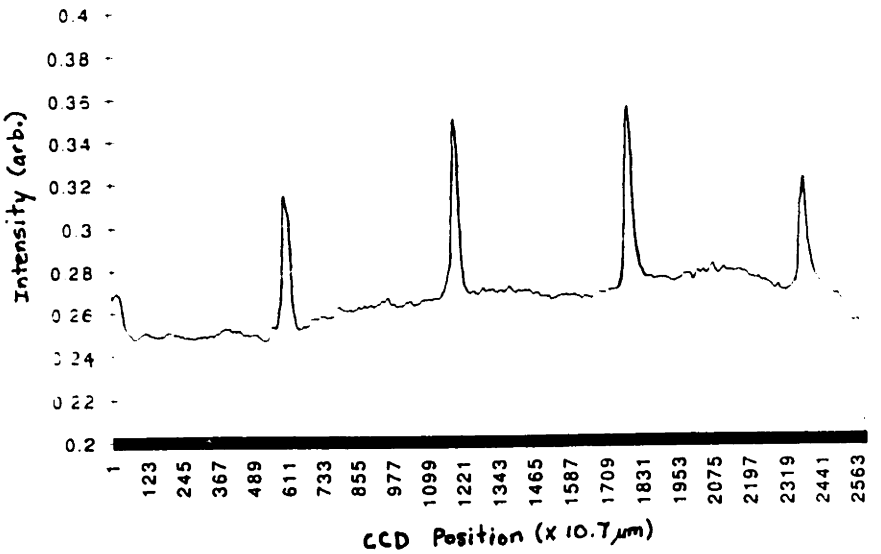


Figure 4.5 Green calibration tube fluorescence image

Transmission reading of the float region

After having calibrated the optical system for both fluorescence and transmission readings, we performed tests using real blood tubes to observe the buffy coat. The first test was a transmission reading using a 16ms CCD exposure time (Figure 4.6). The sharp dip in the middle of the graph indicates the beginning of the float and the other dip-peak-dip (from left to right) indicate platelets, lymphocyte/monocyte, and granulocytes, respectively. The middle of the graph shows non-uniform intensity because of a non-uniform lighting. This problem was corrected for the other experiments.

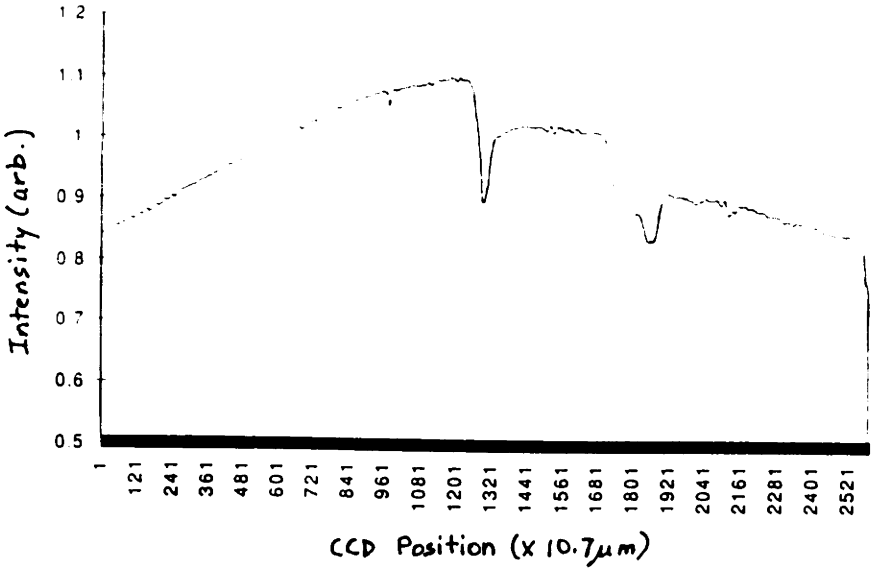


Figure 4.6 Buffy coat transmission reading

Red and Green Fluorescence Readings of Buffy Coat

Red and green fluorescence readings were taken with a blue excitation light source (Figures 4.7 and 4.8). The plateau on the left-side of both graphs represent the plasma region. In the red fluorescence graph, the sudden drop indicates the beginning of the float. The peak-dip-peak are the platelets, lymphocyte/monocyte, and granulocytes, respectively. We found similar readings from other experiments. In the green fluorescence graph, the lymphocyte/monocyte band, which fluoresces green, is clearly shown as a peak. With the two graphs overlapped, the band boundaries were found (Figure 4.9). Laura Edwards conducted an experiment with a single blood tube in both the "CCD Imager" and the QBC® Autoreader machine. She visually inspected the graphs and manually calculated the cell counts from the "CCD Imager" reading. She found a good correlation between the results from the two systems (Table 4.4). A program that can more precisely process the data and calculate the cell differentials ought to provide better results for the "CCD Imager."

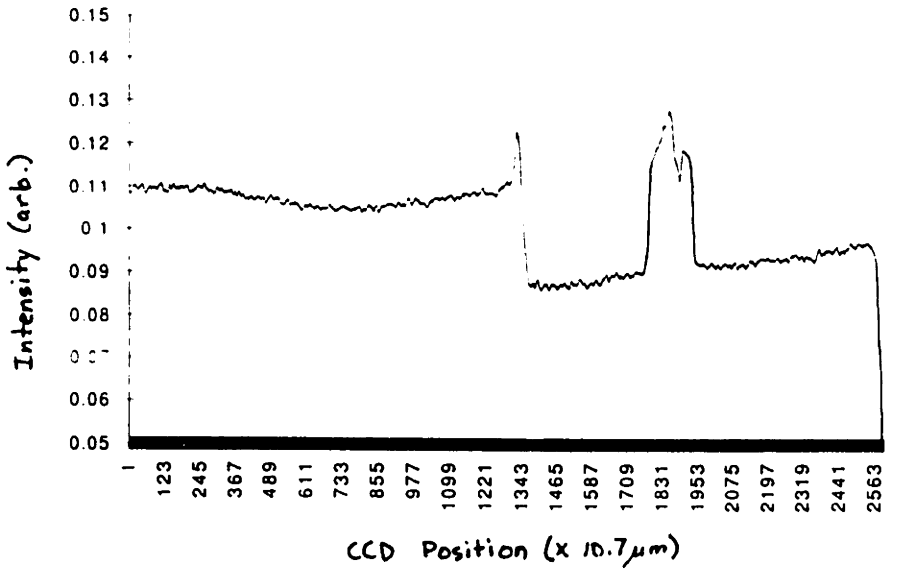


Figure 4.7 Red fluorescence reading of a buffy coat

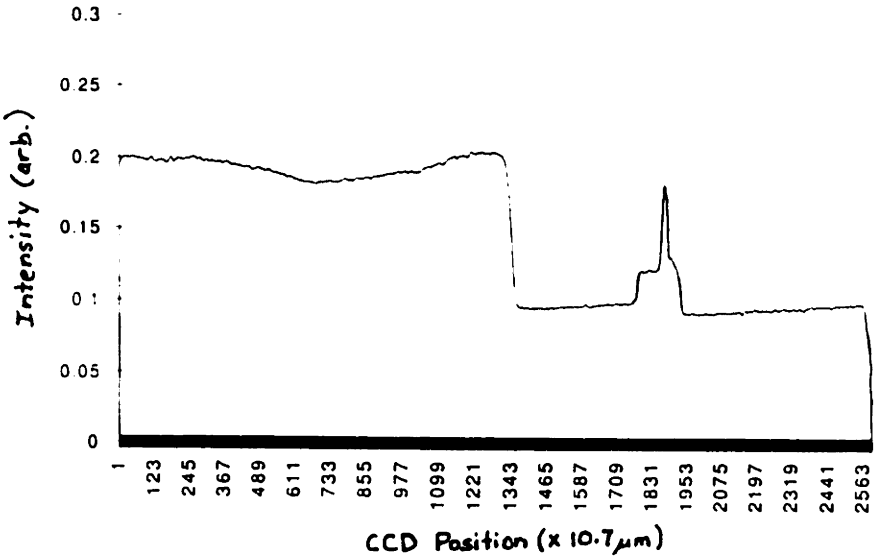


Figure 4.8 Green fluorescence reading of a buffy coat

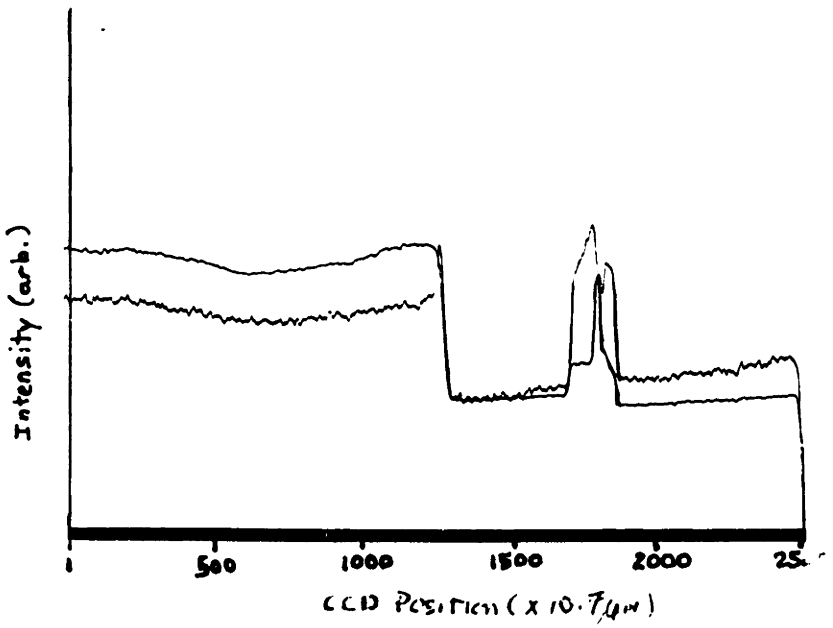


Figure 4.9 Red and green fluorescence readings of a buffy coat overlapped

Blood parameter	QBC Autoreader Results	"CCD Imager" Results
Total WBC (#/L)	7.0×10^9	7.2×10^9
Granulocytes (#/L)	4.8×10^9	3.9×10^9
% Granulocytes	69 %	54 %
Lymph/Mono (#/L)	2.2×10^9	3.3×10^9
% Lymph/Mono	31 %	46 %
Platelets (#/L)	233×10^9	234×10^9

Table 4.4 "CCD Imager" cell counts[41]

Repeatability Test

The optical system repeatability was determined by analyzing a set of 10 transmission readings of a black and white calibration tube. This calibration tube was used because it was able to cover the full intensity range of the CCD. Maximum repeatability was found by comparing every combination of the 10 data files (45 file combinations) each of which contained over 2500 data points that corresponded to the intensity measurements of the CCD pixels. Each data point was compared to the corresponding data point of another data file and repeatability was found using:

$$\%error = \frac{|d_1 - d_2|}{R}$$

where d_1 and d_2 are the corresponding data points from two data files and R is the measured full intensity range of the CCD.

From the 45 data file comparisons, the maximum error between any two points was found to be 0.805% and the average error 0.137%. This high repeatability allows the CCD to potentially achieve an average accuracy of 99.86% by *mapping* the CCD errors.

High Density Barcode Imaging

A high density bar code (approximately 30 ASCII characters per inch) on a clear plastic was placed in the plasma region of a blood tube and read for the purpose of patient identification. The enlarged bar code and its CCD image is shown on figure 4.10. The black bar code lines are represented by wide and thin steps. This result shows great promise for patient identification.

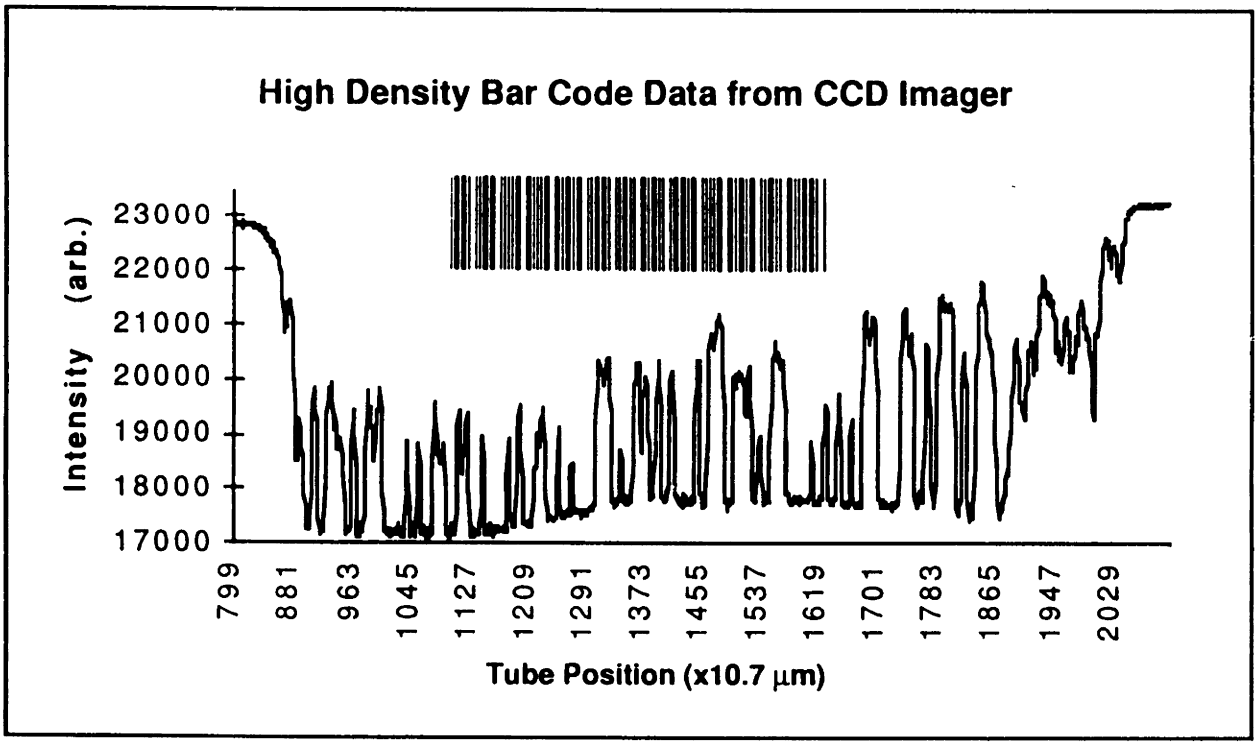


Figure 4.10 CCD image of a high density bar code

4.2.2.2 Conclusion

The results from the experiments showed that the CCD has the necessary dynamic range and precision. The red and green fluorescence graphs clearly show the band boundaries of platelets, lymph/mono, and granulocytes. The system also showed high repeatability with a maximum error of 0.81% and average error of 0.14%. These performance

characteristics make the "CCD Imager" extremely promising for the QBC® Walkaway system.

Our team hopes to use a 1-1/2 inch long 6000 pixel CCD array (manufacturer to be determined) and a JML 2:1 wide-field lens to image an entire 3 inch blood tube with 0.0005 inch precision. Currently, the 5000 pixel CCD's manufactured by Kodak and Sony are our best choice in terms of availability and cost. However, we expect that an inexpensive 6000 or 8000 pixel black and white CCD's which will be able to provide 0.00050 or 0.00038 inch resolution are expected to become readily available in the very near future.

4.2.3 Colorimetric System Trade-Off Study

Our next step was to select a colorimetric system for the "CCD Imager" to perform blood band color analyses. Our choices were a rotating diffraction grating (see figure 3.17) that diffracted the light onto the CCD (Figure 4.2) or a color filter "drum" that rotated about the center of the CCD (Figure 4.11). Experiments with the "CCD Imager" breadboard showed that both ideas were feasible. Vendor and BD information were compiled for a trade-off study.

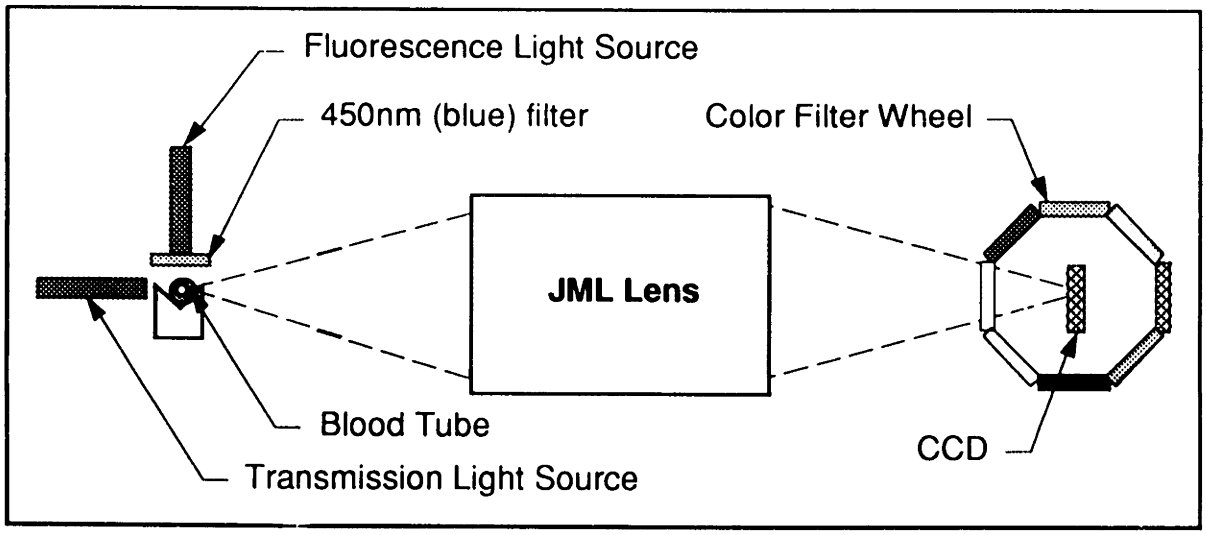


Figure 4.11 "CCD Imager" with color filter wheel

4.2.3.1 Cost Analysis

Eight color tests were assumed based on BD's expectation for additional blood tests in the future. The cost analysis included components specific to each colorimetric system including color filters, diffracttion grating, motors, motor controllers and mounts. The cost was determined to be between $260 and $300 for the color filter system and $200 to $250 for the diffraction grating system in large quantities (Table 4.5). Hence, the diffraction grating system was estimated to be $10 to $100 less expensive.

Component Costs	Color Filters	Diffraction Grating
8 Color filters or 1 Diffraction grating	$120-$160	$20-$30
Motor	$25 (larger but less precise)	$30 (smaller but more precise)
Motor Controller	$35	$50-$90 with encoder
Mounts	Drum and mount $80	Precision bearing and mount $100
TOTAL	**$260-$300**	**$200-$250**

Table 4.5 Colorimetric system cost analysis

4.2.3.2 Performance and Manufacturing Analyses

Assembly, size, speed, efficiency, accuracy, longevity, and versatility issues were also evaluated in detail (Table 4.6). Relative weights of 1 to 10 were given to each system based on vendor information and our team's experiences using both color analysis techniques. The diffraction grating's small size, speed, and versatility made it very desirable despite the lower efficiency and the need for greater mounting precision. It's capability of analyzing a full spectrum of colors with just a software upgrade was found to be very advantageous to BD for future blood assays.

scale : 1-10 - 1=worst, 10=best

CRITERIA	COLOR FILTERS	DIFFRACTION GRATING
Assembly	**6** Filter alignment is important (although not as crucial as with the diffraction grating) to obtain proper wavelength transmission and bandwidth	**5** Once precision parts are made, assembly should not be too much more difficult than with the color filter.
Size	**3** Large drum, larger motor to accommodate larger drum inertia	**10** A small motor and a single diffraction grating is needed. Reflecting of image also reduces overall size.
Speed	**7** A large drum with 8 filters around its circumference will require potentially more time than just rotating with small angles with a diffraction grating.	**9** Only need to rotate the grating at most 180 degrees. But, lower efficiency requires a longer exposure time. This delay might be accommodated by increasing exposure time or increasing the light source intensity.
Efficiency, Accuracy, and Longevity	**6** Color filters are about 80-90% efficient. That is about 2 times more efficient than diffraction gratings. The accuracy of the thickness of the filters affect the accuracy of the transmitted wavelength. Furthermore, filters tend to delaminate after some period of time which will cause wavelength inaccuracies.	**5** The grating only provides about 40-50% efficiency. But, this low efficiency can be accommodated by increasing the CCD exposure time.
Versatility	**4** More color filters can be added to the system in the future. However, there is considerable cost associated with installing and purchasing color filters and software. Furthermore, if in the future, many more colors need to be analyzed, larger drums and more color filters need to be incorporated.	**10** The diffraction grating can accommodate the full spectrum of colors as well as white light (0'th order for transmission readings). Any future assays that will expand the capability of the QBC® Walkaway system can be easily accommodated through software rather than both hardware & software as required with the color filters.

Table 4.6 Colorimetric system performance and manufacturing analysis

4.2.3.3 Colorimetric System Selection Conclusion

After having evaluated numerous aspects of the color filter and diffraction grating, the diffraction grating performed better in many critical categories: including versatility, cost and speed. But, the color filters were found to be slightly more desirable in assembly and efficiency; they end up costing about $10-$100 more than the diffraction grating. Furthermore, they would be more difficult and expensive to upgrade for future assays because new filters will have to be added. The diffraction grating offered the flexibility for easy upgradability with only software upgrades. Its setup was smaller than the color filters because of smaller components and a more compact optical path. Overall, the diffraction grating was determined to be the best choice in terms of cost, performance, and versatility.

4.3 Conclusion

Although we spent close to two months developing the "Fiber scan", "Scanning Mirror", and "CCD Imager" breadboards, we realized that only the "CCD Imager" was the most practical choice. If we had performed an extensive study of the breadboard designs, we might have been able to select the "CCD Imager." However, developing all three breadboards gave us deep insights into the possibility of actual implementing any one of the three systems. The "CCD Imager", which simply focuses a tube's image onto a linear CCD array, was found to be the best system based on low cost, high performance, and simplicity. For blood band color analysis, we decided to use a rotating diffraction grating instead of color filters because of its lower cost, easier ungradability for new blood parameters, simplicity, and smaller size.

5. Final System Configuration

The target market for the QBC® Walkaway hematology instrument has been finalized by Becton Dickinson to include physician practices, hospitals, and laboratories that conduct over 10 complete blood counts per day. To meet the needs of this market, a dual rotor system was determined to be the most desirable. A medium-physician practice can purchase one system whereas a larger practice can purchase several of these inexpensive units. Our team has been focusing on developing this dual rotor QBC® Walkaway system and this chapter describes some of its designs. The details of the final system are still in the process of being defined so some designs presented in this chapter may change.

5.1 QBC Walkaway System Layout

The final current system design has two centrifuges, each of which can be loaded with a carousel at any time (Figure 5.1). When the centrifuges are expeditiously loaded with carousels batched with 20 tubes, the machine can have a maximum achievable throughput (after the first 5 minute centrifuging) of 400 CBC's per hour. But a more realistic maximum throughput is around 300 CBC's per hour including user delays. A $1,000 laser printer that has a 8 pages per minute (ppm) print speed can easily accommodate this high throughput. If the machine is not fully utilized, a less expensive inkjet printer or dot-matrix printer is recommended. The completely analyzed carousels are then released to the exit.

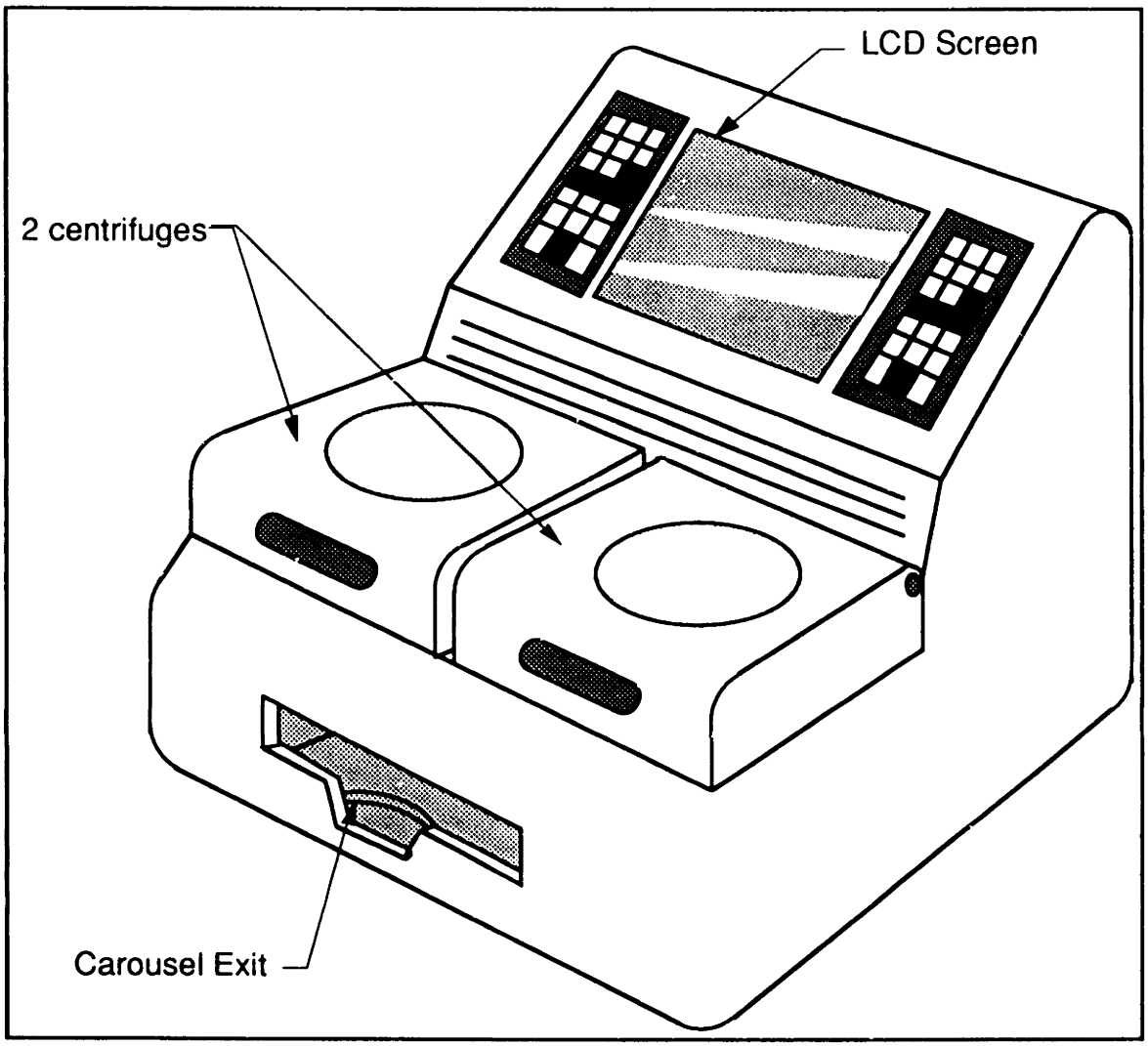


Figure 5.1 Possible System Exterior

A black and white LCD screen displays patients' CBC analyses, quality control, calibration, and any other necessary information. The details of the display such as size, positioning of interactive controls and other human interface aspects of the QBC® Walkaway system will be incorporated in the future after conducting and assessing customer interviews on human interface issues.

The QBC® Walkaway system will have the following features:

- walkaway capability
- 2 centrifuges
- "CCD Imager" and diffraction grating optical reading station
- 20 sample carousels
- automatic patient identification (see section 3.2.1)
- maximum achievable throughput: 400 CBC's per hour (9 seconds per tube)
- accepts both Vacu-Tube and EZ-Prep tubes
- LIS interface capability
- floppy and hard drive for recording patient and quality control information and upgrading software
- serial printer port

5.1.1 Material Handling Trade-Off Study

After having decided on the "CCD Imager", diffraction grating color system and dual centrifuge rotors, the material handling issues were addressed. The following scenario goes through the first steps of material handling inside the system:

1. Each centrifuge rotor accepts a standard carousel (Figure 5.2) which has a maximum capacity of 20 samples.

2. After a carousel is inserted, a rotor cover will automatically actuate to enclose and isolate the carousel to contain blood aerosols and glass particles in the event that a tube breaks during centrifugation.

3. For the next step, we had to decide on one of the three possible methods for reading tubes:

   - leaving the carousel in the rotor and moving individual tubes to the optical reading station
   - moving the entire carousel to the optical reading station, or
   - reading the tubes directly in the rotor.

Amy Battles conducted the trade-off study among these three alternatives for reading tubes. A summary of our decision is presented below.

Ideally, we would like to eliminate any possibility of blood contamination by keeping the tube and the carousel in the rotor. However, this requires moving the optical reading station from one rotor to the other which increases the need for interior space. Continual motions can increase the possibility of misaligning the precision optical components. The unreliability and limited space made this concept impractical.

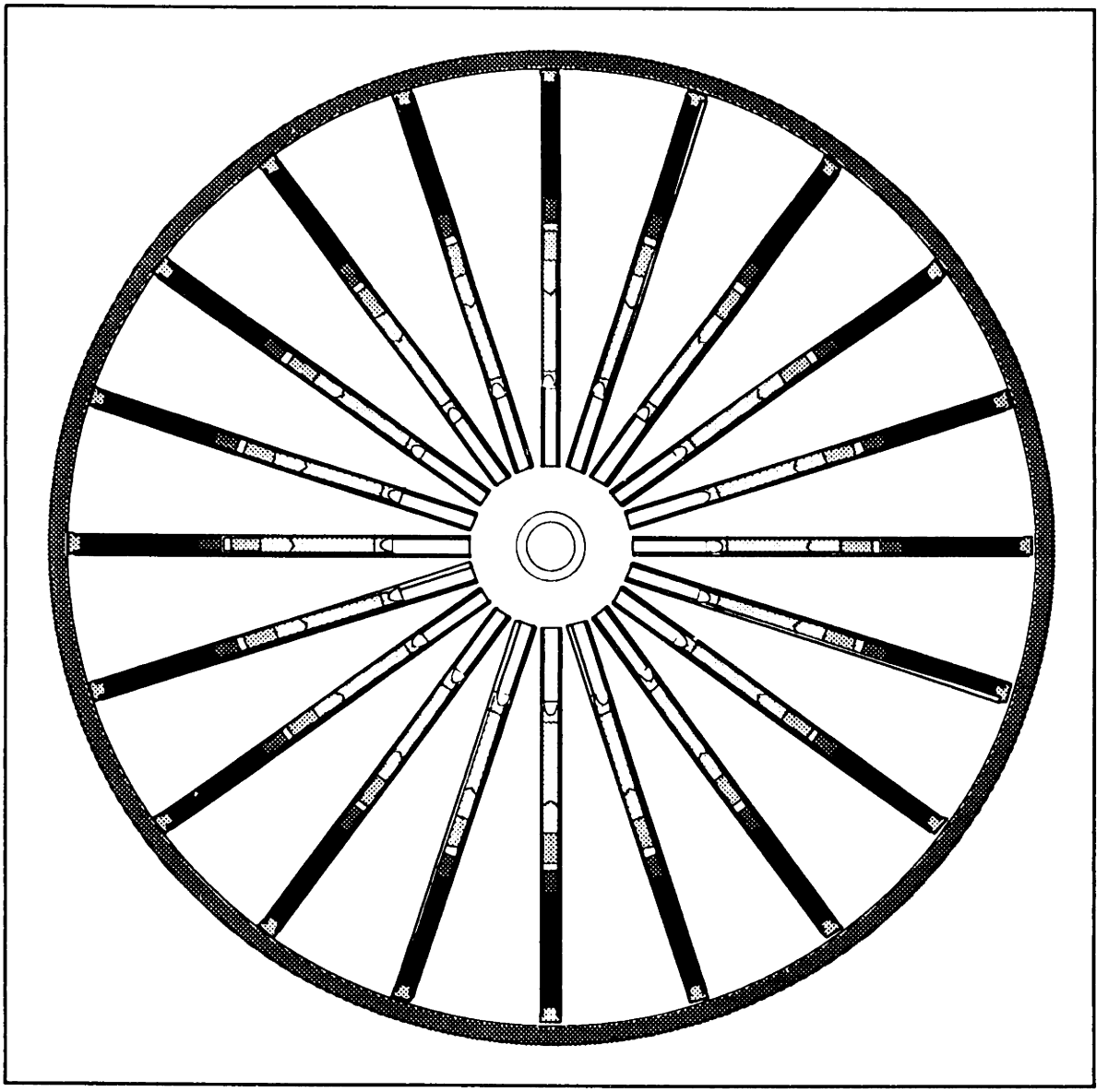


Figure 5.2 Full carousel of EZ-Prep tubes

Moving one tube at a time from the rotor to a stationary optical station has several problems. It is possible to contaminate the system if a tube is accidentally dropped or breaks during transport. The capillary tube's small diameter (approximately 3/32 inch) and its fragility makes it difficult to reliably move the tube.

The best concept was to move the carousel to the reading station. The optical reading station and other mechanical components for rotating the tube are located outside of the centrifuging area. A solid-bottomed carousel

can reduce the possibility of machine contamination because it will contain any broken tubes and blood. If a *clear-bottomed* carousel is used, both transmission and fluorescence readings can be performed. Furthermore, throughput can be increased to satisfy high-volume CBC customers. While a carousel is analyzed by the optical station, two other carousels can be centrifuged simultaneously. After completing the analysis, the carousel in the optical reading station can be released to an alternate exit rather than being returned to the rotor. The advantageous attributes are greater machine throughput, contamination containment, and a stationary optical reading station. Our team has agreed to move the carousels to the optical reading station in the QBC® Walkaway system prototype.

5.1.2 Internal System Description

Figure 5.3 shows the current internal layout of a QBC® Walkaway system design; this is only a possible configuration. After a carousel has been inserted and the machine cover is closed, the self-sealing and self-locking rotor cover (situated in the machine cover) automatically lowers itself onto the centrifuge rotor. Each centrifuge is isolated by a protective enclosure (not shown in figure 5.3). After 5 minutes of centrifuging, the cover automatically opens the rotor.

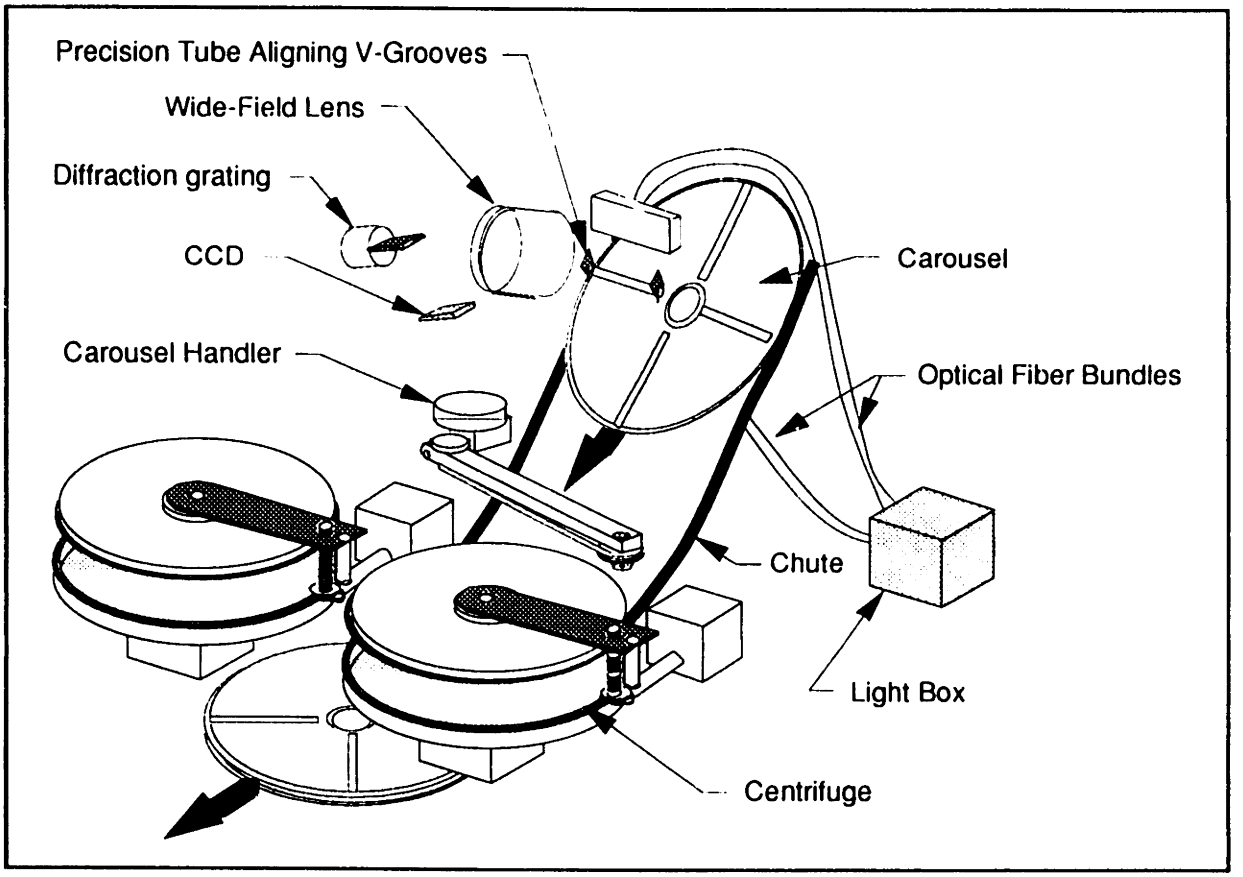


Figure 5.3 Internal system layout

The carousel handling arm is integrated with actuators for moving the carousel, rotating the carousel, and indexing the tubes. After centrifuging, the carousel handling arm rotates into the centrifuge protective enclosure, picks up the carousel, and carries it to the optical reading station. While in the reading station, a tube is located by some optical tube detecting mechanism, the carousel is rotated, and the carousel is lifted to permit the tube to automatically align itself into focus in the precision V-grooves (Figure 5.4). While reading, the tube is *indexed* eight times and patient ID is scanned into the system. Then the carousel is lowered and the next tube is *sequenced* for reading. After collecting data from all the blood tubes, the carousel is dropped onto a chute and slides down to the exit. The analyses are performed by the system computer (IBM compatible 486 system) and the information is downloaded to the LCD display, the printer, and the LIS, if desired.

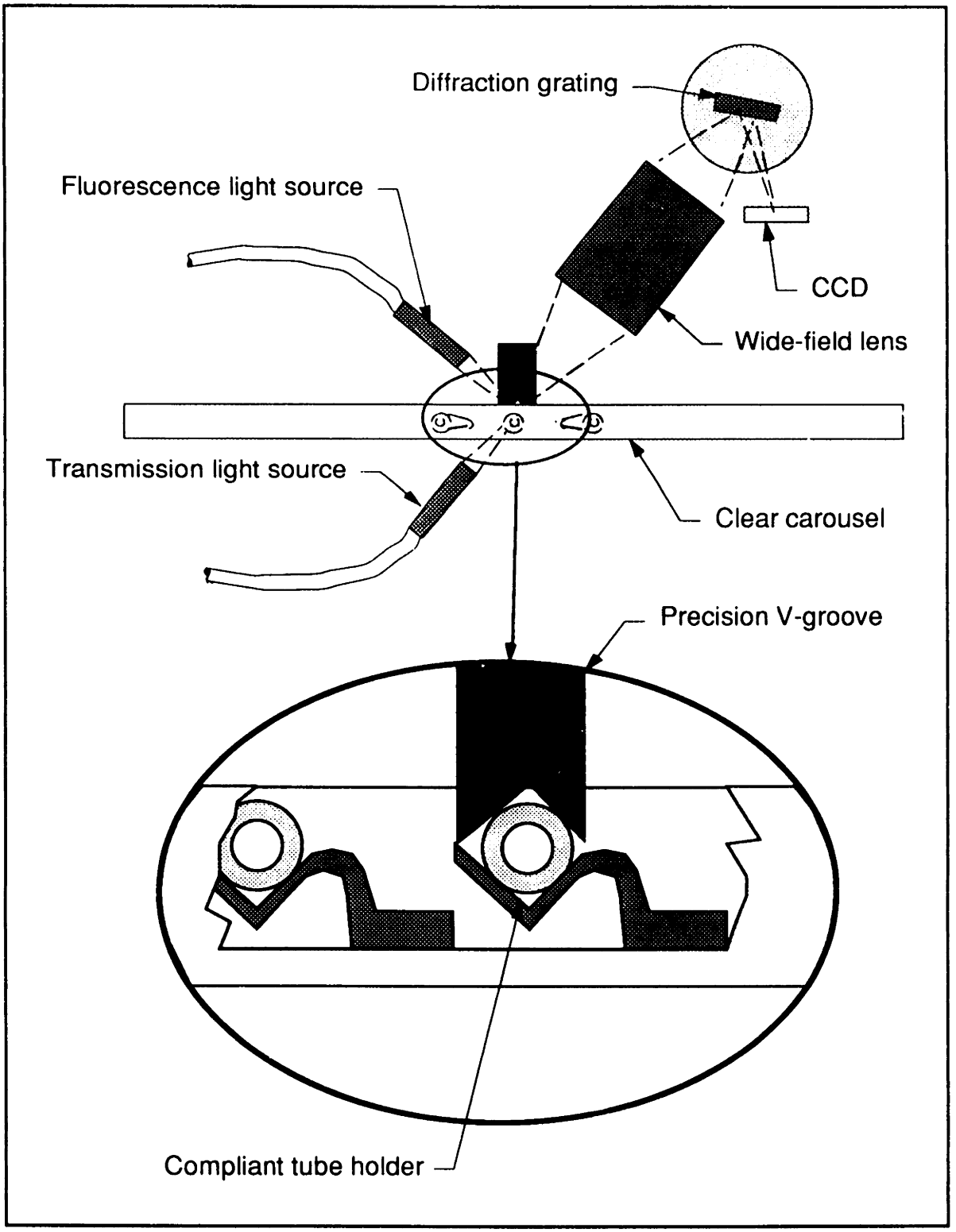


Figure 5.4 Optical reading station

5.1.3 Self-Locking and Self-Sealing Rotor Cover Design

With the current QBC® Autoreader system, a separate cover is manually placed on the World Class centrifuge rotor and it is tightly fastened with a thumb screw. It is possible to start the centrifuge after forgetting to replace the cover or failing to tightly fasten the thumb screw. A loosely tightened cover can unscrew from the rotor's high angular acceleration. When this occurs, blood tubes can fly out of the rotor and contaminate the centrifuge compartment with blood and broken glass. In this situation, the medical technician can become exposed to potentially hazardous blood while trying to decontaminate the centrifuge compartment. Another option for the medical technician is to return the centrifuge to BD and wait a few days until a decontaminated centrifuge is returned. Centrifuge contamination creates a hazardous environment for the medical technician, handlers during shipping, and also inconveniences the doctors and patients who need blood analysis results for expediting patient diagnoses.

An automatically actuated rotor cover has been designed into the Walkaway system to eliminate the possibility of contamination. The cover shown in figure 5.5 uses centrifugal force to lock and tightly seal the centrifuge. The self-locking and self-sealing features prevent contaminants or sharp glass particles from escaping the rotor in the event of blood leakage or glass tube breakage during and after centrifugation. There are several spring-loaded pawls around the circumference of the rotor cover which snaps into the grooves of the rotor. The o-ring, around the circumference of the cover, isolates the contents of the rotor to the system at all stages of centrifugation. The mechanical closure created by the cover resting on the rotor's inner flange prevents glass particles from leaving the rotor. As the centrifuge accelerates, the pawls move outwards and their cam action forces the rotor and cover together. Also, the o-ring tends to move radially outward which creates an even tighter seal as it becomes wedged between the cover and the rotor. The pawls and the o-ring utilize the centrifugal force to contain contaminants and to hold down the cover in a simple and effective manner.

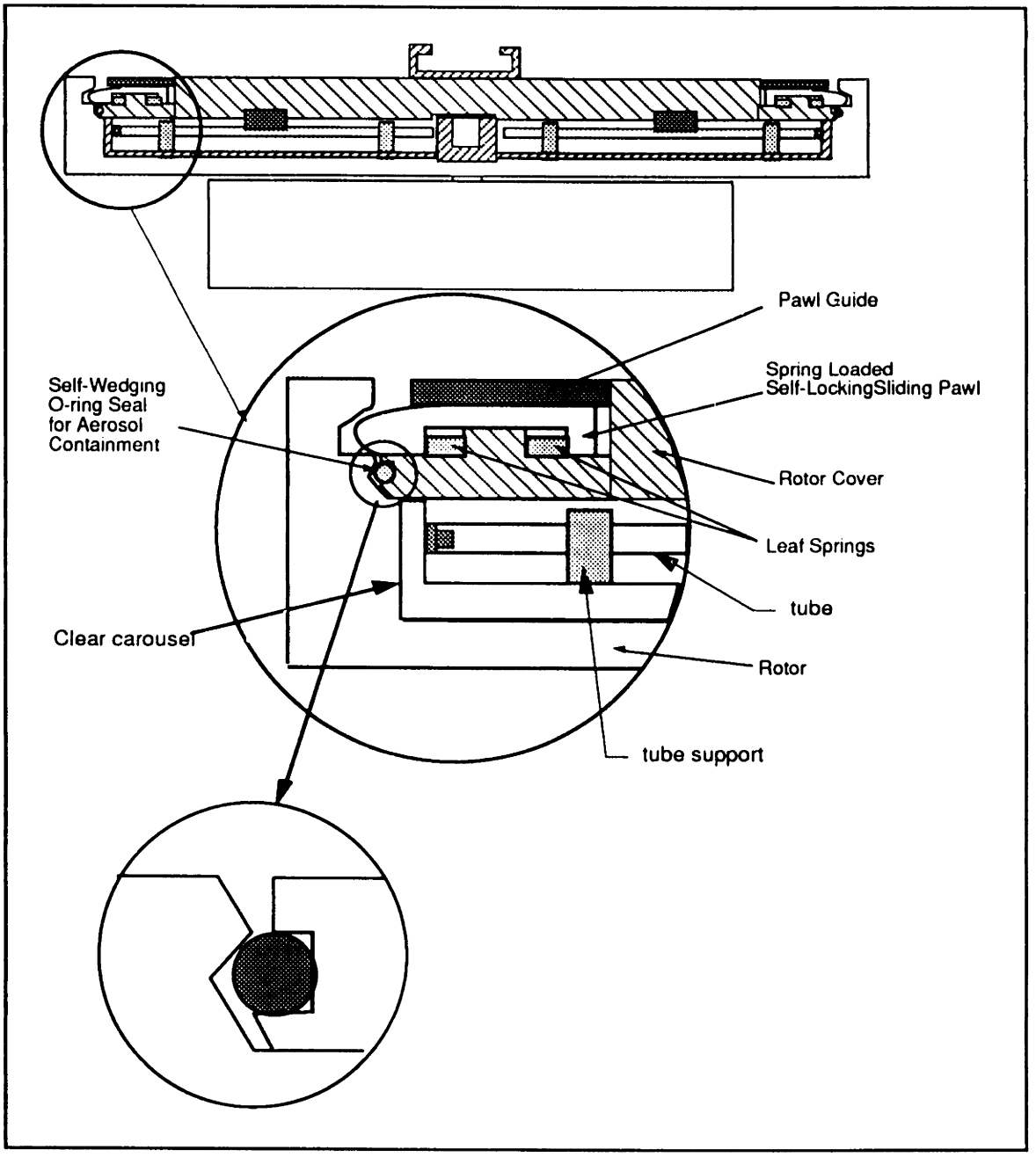


Figure 5.5 Self-sealing and self-locking centrifuge cover design

5.1.4 Carousel Handling Mechanism

The carousel handling mechanism can perform several functions (Figure 5.6); it can pick up the carousel after centrifuging, move it to the optical reading station, *index* the tubes and *sequence* the carousel. The pitch actuator lowers the arm and the latch actuator picks up the carousel; the yaw

actuator moves the carousel to the optical reading station; and the tube handling mechanism *indexes* the tubes and *sequences* the carousel. After all the tubes in the carousel have been read, the carousel is automatically released onto the chute where it slides down to a front exit.

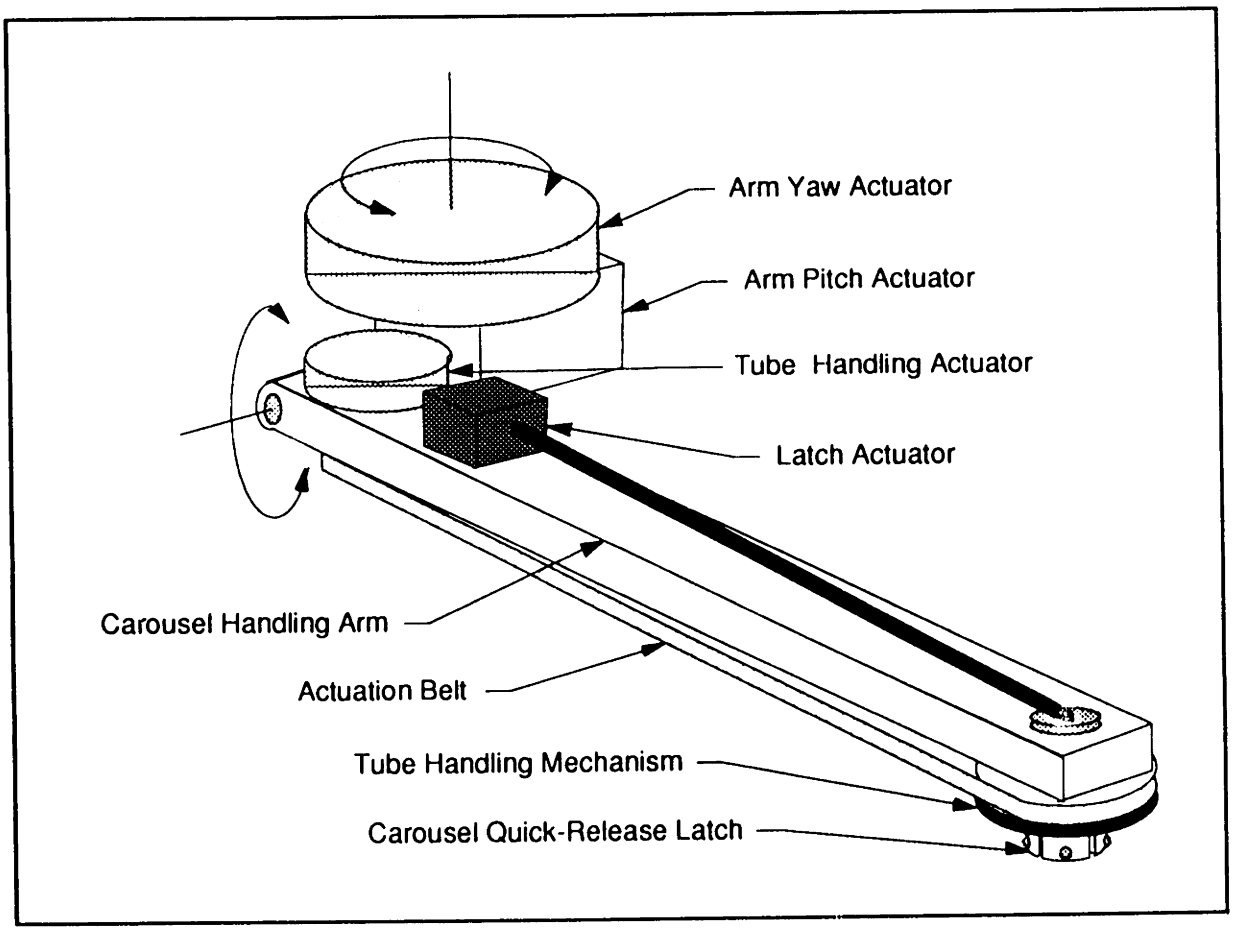


Figure 5.6 Carousel Handling Mechanism

Carousel Quick-Release Latch Design

The head of the carousel handling mechanism contains a quick-release latch. The latch has prongs which expands outward to latch onto the carousel when the wedge is pulled up (Figure 5.7). Once in the optical reading station, a roller clutch permits one motor to index tubes when rotated in one direction and also sequence the carousel when rotated in the opposite direction. The spring maintains a constant pressure on the friction roller to

effectively index the tubes. The friction roller is an o-ring but its material has not been finalized. The o-ring material will be selected to maintain resilience and friction over a long period of time in the presence of dirt and wet & dry blood.

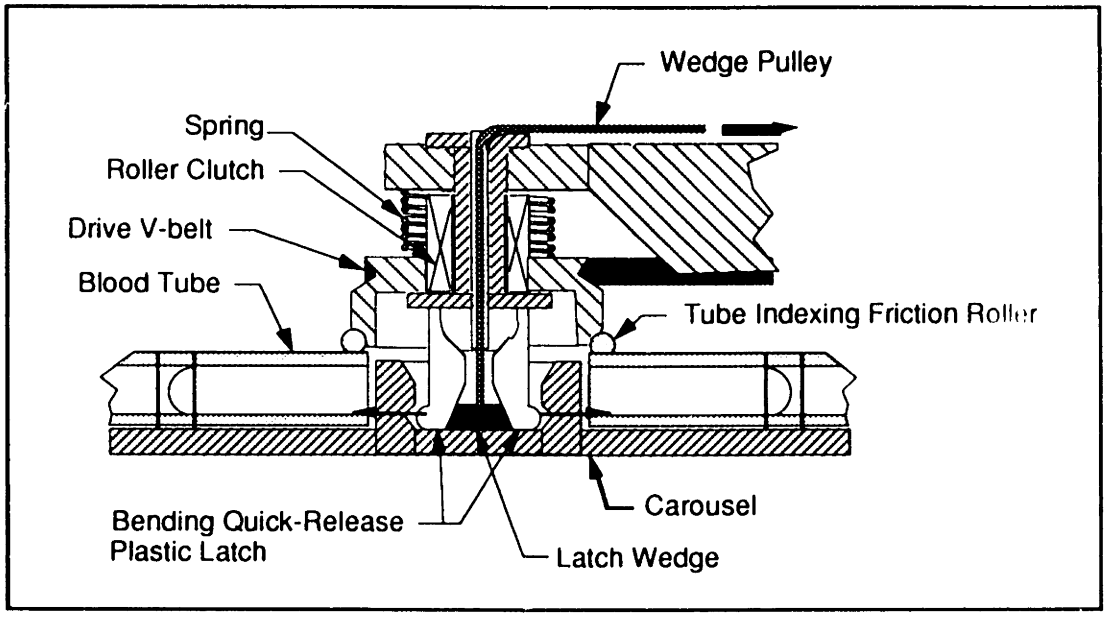


Figure 5.7 Carousel Quick-Release Latch

5.2 Conclusion

The final system details are still being defined and designed. The designs that were presented in the previous sections were representative examples of the Walkaway system that I have designed. Amy Battles and Andres Pieczanski will be involved in further designing and developing the mechanical systems of the first prototype. Along with Amy and Andres, Professor Woodie Flowers and Erik Vaaler, PhD., a lecturer and a mechanical designer at the MIT Mechanical Engineering Department, will aid in the system designs. During the course of the project, the system's mechanical designs are expected to change.

Laura Edwards and David Otten will be developing the "CCD Imager" optical system and its associated electronics and software. The optical system set-up is being designed by Ming Wu.

Nanette Palmer and Karon MacLean are still interviewing customers with the SUPERCARD™ simulations. After these interviews, the customers' voices will be assessed to develop the human interface aspects of the machine.

Babu Anisetti and BD will continue to with the market research to concretely define the final system. Several focus groups are expected to be held by BD to firmly establish the needs of the medium-physician (3-10 physicians) market.

6. Group Dynamics

Product development team's group dynamics is critical to the success of a product.[42] It's important that the team members interact and communicate effectively and understand each other's area of discipline. During the beginning of the product development cycle, our team spent a lot of time educating each other in our respective disciplines; the engineering students learned about marketing and the marketing student learned about design engineering. We were fortunate to have a marketing graduate student, Rich Wong, who already had exposure to engineering as an engineering undergraduate from MIT. As we became more acquainted, we developed mutual respect and agreement was easier to reach.

We all had many chances to take leadership roles by mediating various discussion topics during many of the QFD processes. Everyone made substantial contributions to the decision-making process when it was necessary to making our meetings more productive. Dr. Michael Rosen (now an associate professor at the University of Tennessee), the project manager, headed many meeting discussions and resolved group conflicts and arguments effectively.

The team became close through social activities such as camping trips and house parties. Humor during long meetings eased tensions and stimulated creativity. The friendships created in the team provided

motivation and support. The friendly and professional atmosphere made the team environment very comfortable, enjoyable, and productive.

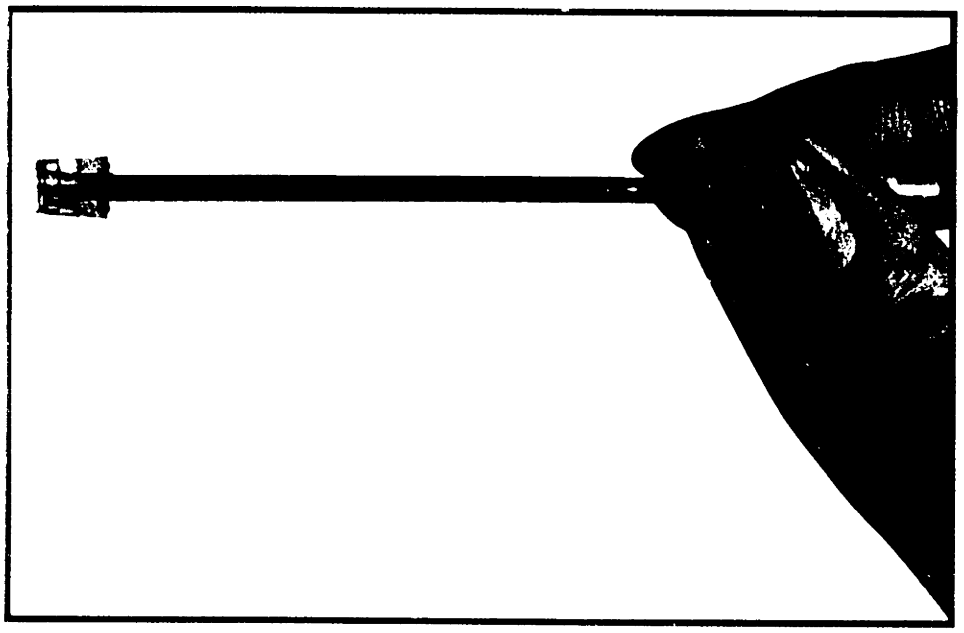
For the first several months, we did not have an effective communications channel between BD (in Sparks, Maryland) and our team. We resolved this issue by establishing an electronic mailbox in the MIT Athena computer system where everyone associated with the BD project freely exchanged information. Being in contact with BD on a daily basis helped to expedite information flow. We were fortunate to have a corporate member, Brad Thomas (now the project manager of the QBC® Walkaway system), who kept in touch with the team on a daily basis and essentially became part of our MIT product development team. Electronic mail also allowed every team member to communicate with eachother. Electronic information flow tremendously improved our efficiency in decision-making and kept everyone in touch with many aspects of the project on a daily basis. Understanding everyone's issues and positions increased the effectiveness of our multi-disciplinary product development team.

As each of us championed a breadboard, we switched to more individual work. This allowed us to concentrate for greater effectiveness on developing the breadboards. Although we did not communicate as much during this phase, we were able to share our work with each other during the weekly meetings.

Appendix A

QBC® Machine Description

Becton Dickinson Brings You The Award-Winning QBC® Technology



NOW WITH HEMOGLOBIN!

Hematology parameters as easy as a spun hematocrit

- Hemoglobin
- Hematocrit
- Platelet Count
- Total White Blood Cell Count
- Total Granulocyte Count
- % Granulocytes
- Total Lymphocyte/ Monocyte Count
- % Lymphocytes/ Monocytes

QBC®: The Unique Buffy Coat Analysi

Hematology parameters as easy as a spun hematocr

1. Platelet Count
Stained platelets comprise the lightest-density layer of the buffy coat. The length of this band is converted into a numerical platelet count value, displayed as "PLT×10³/L."

2. Total Lymphocyte/Monocyte Count

3. Percentage Lymphocytes/Monocytes
Stained lymphocytes and monocytes comprise this segment of the buffy coat. The length of this band is converted by the microprocessor into a Total Lymph/Mono Count, displayed as "LYMPH/MONO×10³/L." This subgroup is also expressed as a percentage of the total white cell count, displayed as "% LYMPH/MONO."

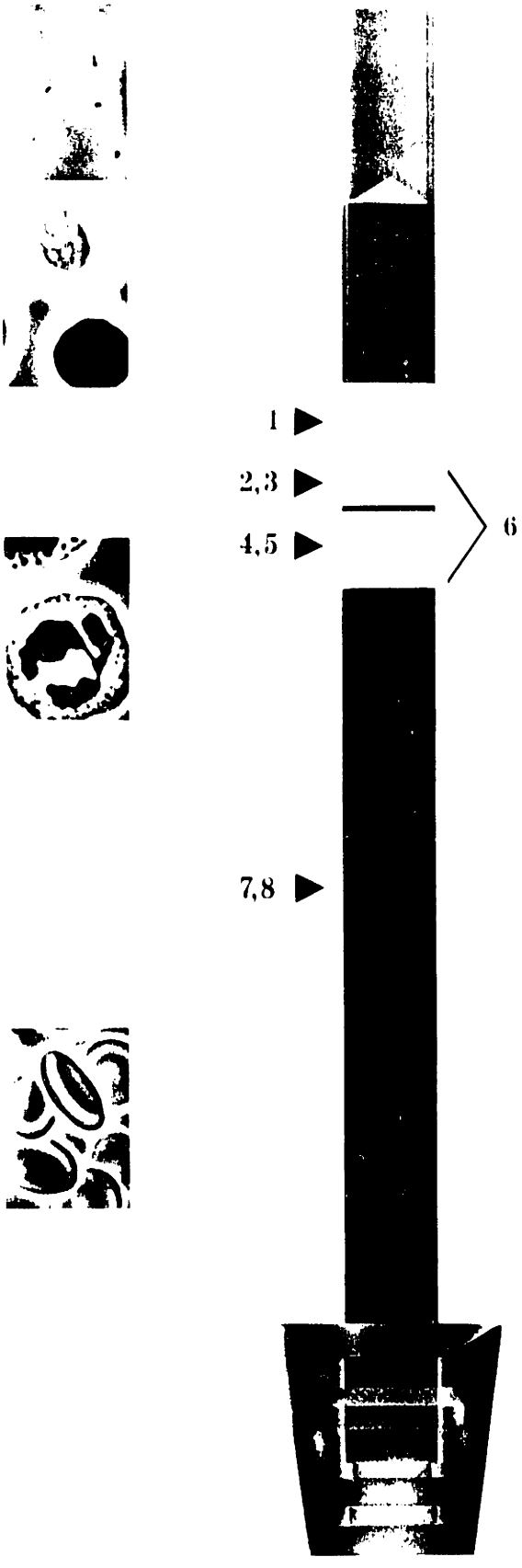
4. Total Granulocyte Count

5. Percentage Granulocytes
This buffy coat segment consists of granulocytes (neutrophils, eosinophils, basophils). The length of this band is converted into a Total Granulocyte Count, displayed as "GRANS×10³/L." This subgroup is also expressed as a percentage of the total white cell count, displayed as "% GRANS."

6. Total White Cell Count (WBC)
This parameter combines the total granulocyte and lymphocyte/monocyte measurements, displayed as "WBC×10³/L."

7. Hematocrit
Two bands of red cells are measured together to determine the hematocrit reading: The first band segment consists of packed red cells; the second (and lighter) band consists of red cells surrounding the base of the QBC tube float. The hematocrit determination is then displayed as "HCT%."

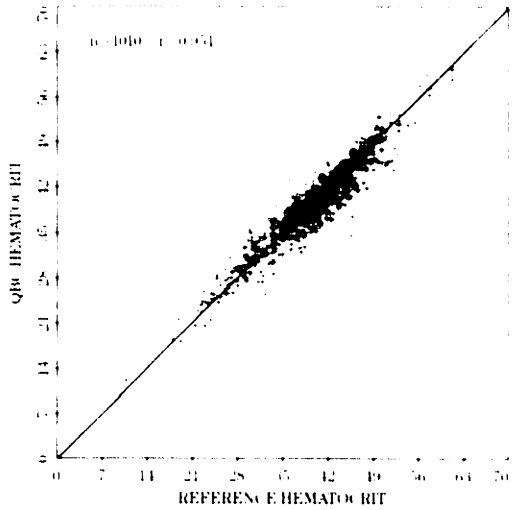
8. Hemoglobin
The depth that the expansion float descends into the packed red cells is a function of red cell density, which correlates with hemoglobin concentration. This relationship permits the calculation of hemoglobin from the float depth and hematocrit. Hemoglobin concentration is displayed as "HB (g/dL)."



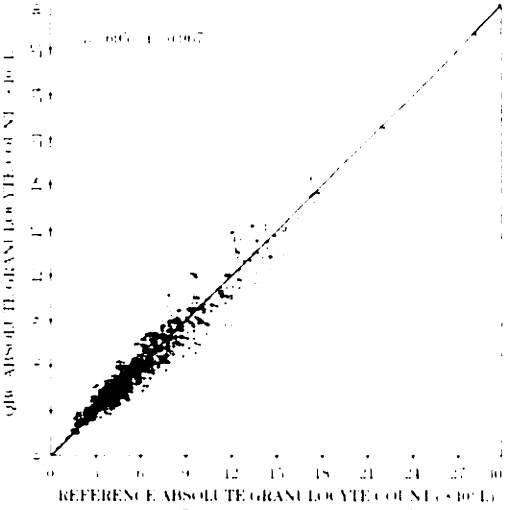
Designed By Physicians...For Physicians

Accuracy comparable to standard reference methods

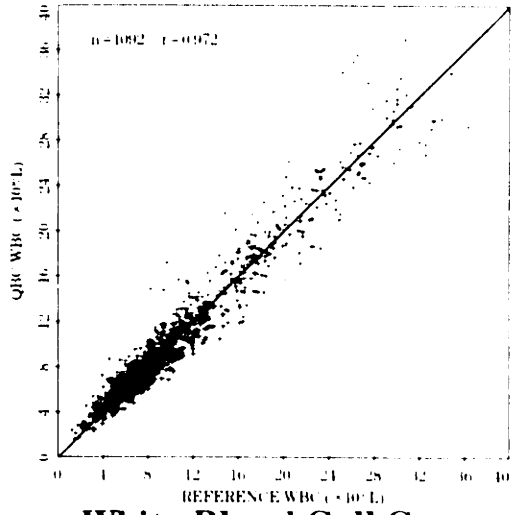
Results of Clinical Trials



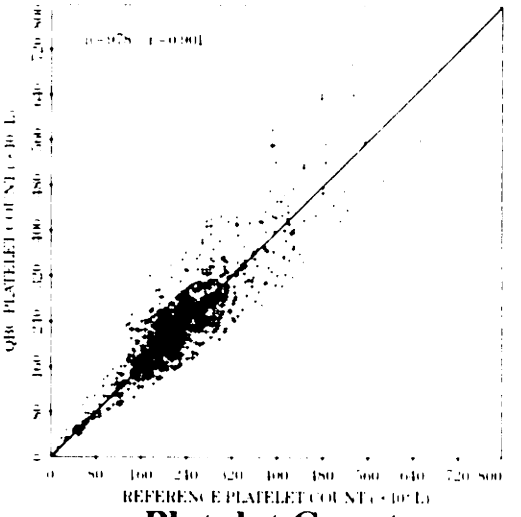
Hematocrit



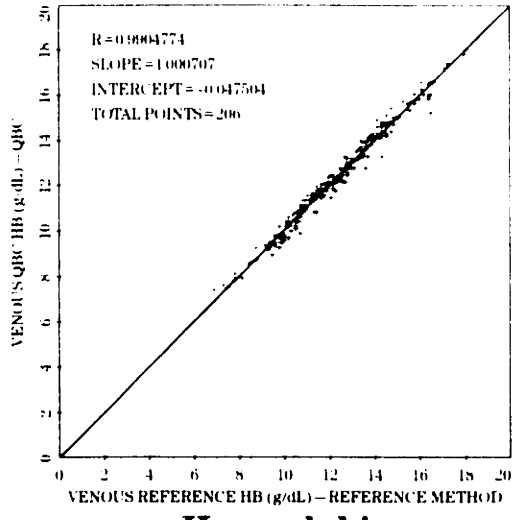
Absolute Granulocyte Count



White Blood Cell Count



Platelet Count



Hemoglobin

The samples shown represent the combined results of studies performed at eight different U.S. locations. At least two individuals performed the testing at each location. The combined studies utilized several instrument models and many different lots of reagent tubes.

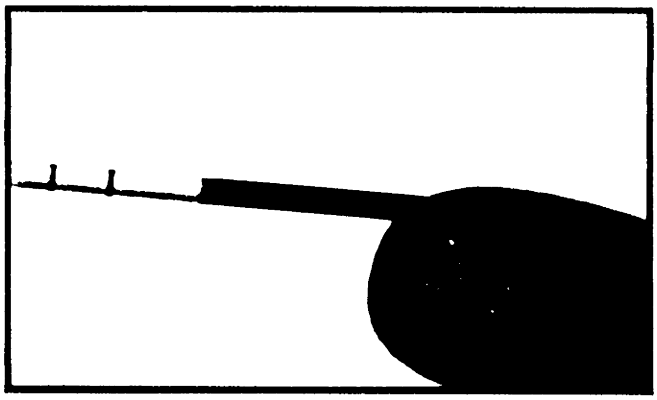
Reference values obtained for the various parameters included the following methods: COULTER MODEL S PLUS, COULTER MODEL S, COULTER ZBI, ORTHO ELT8, CLAY ADAMS ULTRA-FLO 100, spun microhematocrit, NCCLS cyanmethemoglobin method and/or a 100-cell manual differential count.†

†Data on file

Easy QBC® procedure provides hematology results in 3 simple steps — just like spinning a hematocrit.

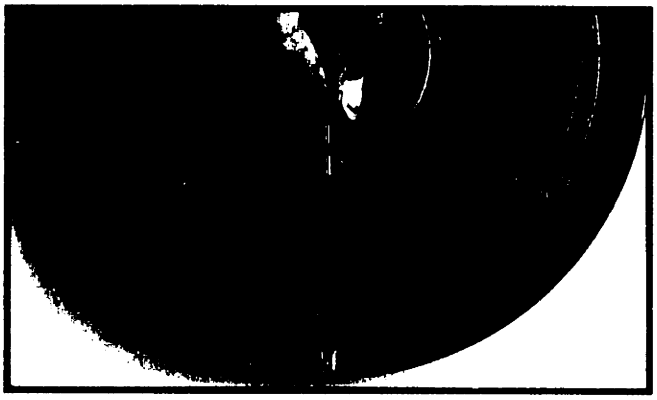
1. Collect blood

- Reagent-coated QBC tube is ready to use
- Fingerstick or venous sample
- Insert float and cap



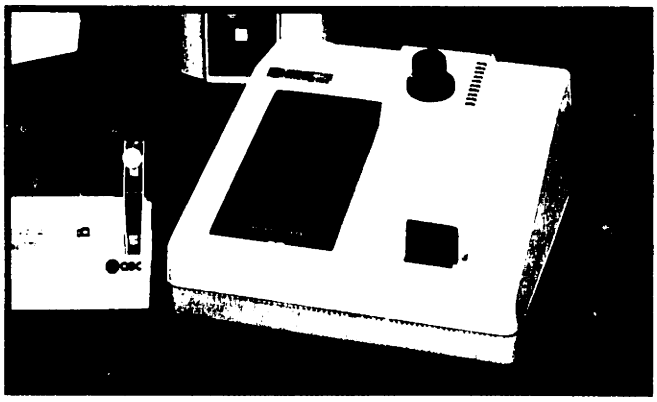
2. Centrifuge

- Spin for 5 minutes in the QBC centrifuge supplied with the system



3. Read/record results

- Tube is easily read in less than one minute
- Instant digital display of all 8 parameters



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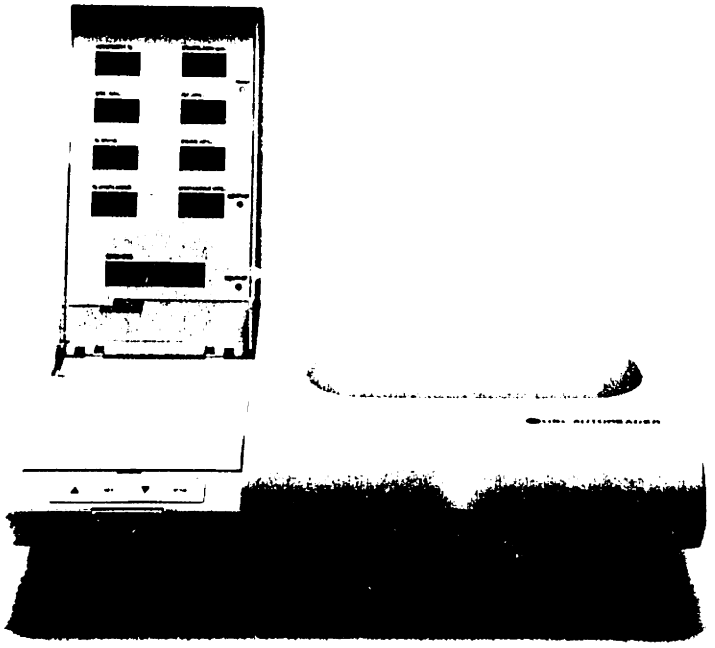
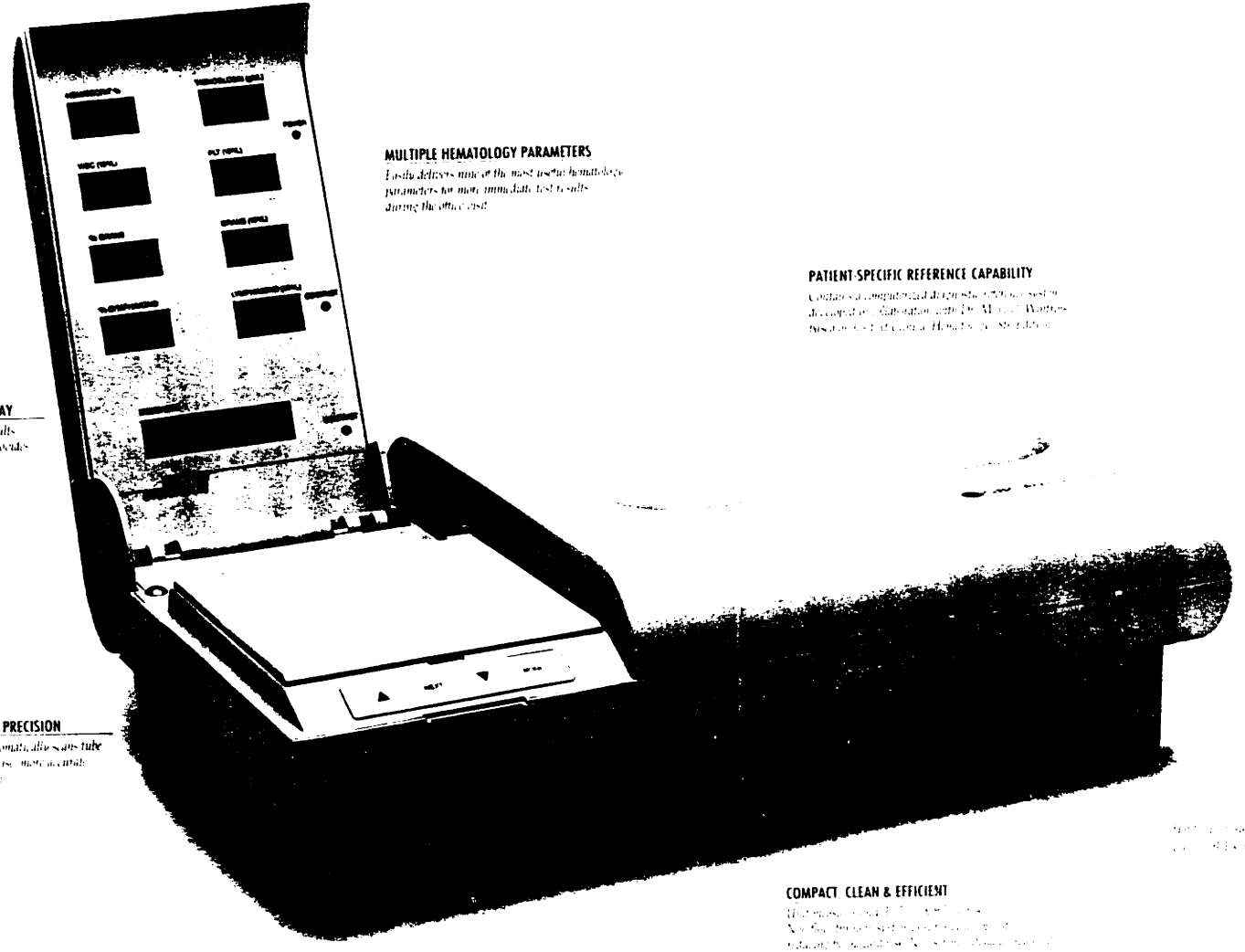


QBC® AUTOREAD
Centrifugal Hematology System

QBC® AUTOREAD System delivers accurate, in office CBCs without the wait.



MULTIPLE HEMATOLOGY PARAMETERS

Easily delivers nine of the most useful hematology parameters for more immediate test results during the office visit.

PATIENT-SPECIFIC REFERENCE CAPABILITY

Contains a computerized diagnostic [illegible] developed by Laboratory Corporation of America® Holdings in Burlington.

CONVENIENT, EASY-TO-READ DISPLAY

Screen flips up for digital readout of results and flips down when not in use. Also provides user prompts and error messages.

10 SCANS FOR MAXIMUM PRECISION

Breakthrough technology automatically scans tube 10 times to provide more precise, more accurate results with no user operation.

COMPACT, CLEAN & EFFICIENT

[illegible]

REMARKABLY EASY TO OPERATE

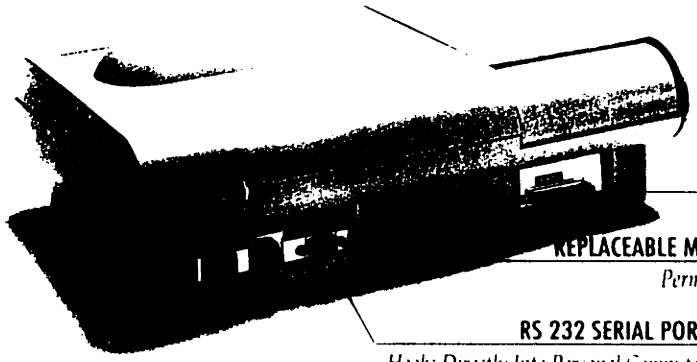
[illegible]

SIMPLE STEPS FOR AN ACCURATE CBC.

Prepare sample

Analyze sample / print results

SPECIFICATIONS



ELECTRICAL INPUTS:
± 16.5 VDC, + 20VDC, + 12.5 VDC.

DISPLAYS:
Reflective-type, liquid crystal.

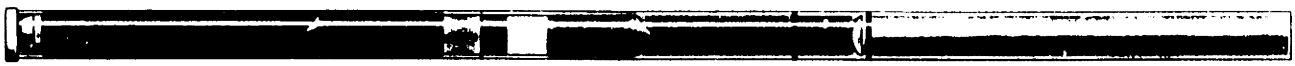
TEMPERATURE REQUIREMENTS FOR QBC TESTS:
20° C to 32° C (68° F to 90° F).
Relative humidity: 10% to 95% *(non-condensing)*

NON-OPERATING STORAGE TEMPERATURE LIMITS:
-20° C to +60° C (-4° F to 140° F).

WEIGHT:
3.6 kg (8 lbs).

DIMENSIONS:
34.3 cm W x 24.13 cm D x 10.2 cm H
(13.5 in. W x 9.5 in. D x 4 in. H)

9 USEFUL BLOOD PARAMETERS – STAT!



QBC® E-Z Prep™ tube

1. Platelet Count Stained platelets comprise the lightest-density layer of the buffy coat. The length of this band is converted into a numerical platelet count value, displayed as "PLT × 10^3/L."

2. Total Lymphocyte/Monocyte Count Stained lymphocytes and monocytes comprise this segment of the buffy coat. The length of this band is converted by the microprocessor into a Total Lymph/Mono Count, displayed as "LYMPH/MONO × 10^3/L."

3. Percentage Lymphocytes/Monocytes Lymphocytes and monocytes can also be expressed as a percentage of the total white cell count, displayed as "% LYMPH/MONO."

4. Total Granulocyte Count This buffy coat segment consists of granulocytes (neutrophils, eosinophils, basophils). The length of this band is converted into a Total Granulocyte Count, displayed as "GRANS × 10^3/L."

5. Percentage Granulocytes Granulocytes can also be expressed as a percentage of the total white cell count, displayed as "% GRANS."

6. Total White Cell Count (WBC) This parameter combines the total granulocyte and lymphocyte/monocyte measurements, displayed as "WBC × 10^3/L."

7. Hematocrit Two bands of red cells are measured together to determine the hematocrit reading: The first band segment consists of packed red cells; the second (and lighter) band consists of red cells surrounding the base of the QBC tube float. The hematocrit determination is then displayed as "HCT%."

8. Hemoglobin The depth that the expansion float descends into the packed red cells is a function of red cell density, which correlates with hemoglobin concentration. This relationship permits the calculation of hemoglobin from the float depth and hematocrit. Hemoglobin concentration is displayed as "HB(g/dL)."

9. MCHC Hemoglobin/hematocrit × 100.

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QBC® Capillary Blood Tubes

Product Information and Test Procedures

For Testing With Becton Dickinson QBC-Series Centrifugal Hematology Systems

INTRODUCTION

NOTICE

USE THESE TUBES ONLY WITH CAPILLARY BLOOD. WITH VENOUS BLOOD USE CATALOG NO. 4240 QBC TUBES.

Intended Use

QBC Capillary-Blood Tubes are designed exclusively for use with the Becton Dickinson series of QBC Centrifugal Hematology Systems. QBC is a blood screening method which yields the following hematology values from a centrifuged blood tube:

- Hematocrit (HCT),
- Hemoglobin (HB),*
- Platelet Count (PLT),
- White Blood Cell Count (WBC),
- Granulocyte Count (% and number), and
- Lymphocyte/Monocyte Count (% and number).

The QBC Platelet Count, White Cell Count and counts of the white-cell subgroups are estimates derived from measurements of packed cell volumes in the centrifuged QBC blood tube. Some disease states are characterized by the presence of abnormal WBC types and yet may yield normal quantitative relationships of Granulocytes to Lymphocytes/Monocytes. The QBC method cannot discriminate between normal and abnormal cell types.

Hemoglobin (HB) is displayed only on the **QBC® II Plus Reader and on Readers specially converted to compute hemoglobin.*

Summary and Explanation

It has been known for many years that the grayish-white buffy coat in the hematocrit tube (Figure 1) contained packed layers of leukocytes and platelets.[1]

In color and thickness, the gross appearance of the buffy coat has long been of interest to clinical hematologists. Wintrobe[1,2] reported approximate correlations between the thickness of the included packed cell masses and the total leukocyte and platelet counts. Olef[3] additionally found that the buffy coat thickness provided an index to the total number of platelets circulating in the blood.

Bessis[4] and Davidson[5] subsequently identified discrete white cell layers within the total leukocyte mass of the buffy coat, which formed according to the different densities of the included white cell types. Zucker and Cassen[6] later confirmed that the layering out of leukocytes occurred in their order of increasing density, namely, monocytes, lymphocytes, and granulocytes.

Histochemical studies by Jackson[7] and others established the metachromatic fluorescence of certain blood cells and their ultrastructures when treated with the supravital fluorochrome Acridine Orange (AO). It was observed that white cells and platelets could be readily distinguished from each other by virtue of their characteristic fluorescence. Mature red cells, however, showed no up-take of the stain and, under blue-violet light, retained their characteristic dark red appearance.

The QBC method utilizes differential metachromatic fluorescence of AO-treated blood cells and density gradient cell layering within the buffy coat to measure the separated packed volumes of red cells, white cells and platelets. Layer measurements are made in an electro-optical QBC Reader instrument, which computes and displays the Hematocrit, Platelet Count, WBC, and subgroup counts of Granulocytes and Lymphocytes/Monocytes.[10]

Hemoglobin concentration (in applicable Readers only) is derived from the hematocrit and measurements of red cell density. In traditional hemoglobinometry, the absorbance of cyanmethemoglobin is measured to determine HB.

Principles

QBC Capillary-Blood Tubes are 75 mm in length. Tubes are filled by capillary action directly from a finger puncture to a level between two black lines imprinted on the tube. Design fill volume is 55 to 65 µl. During the tube reading sequence, the actual volume of specimen drawn into the tube is determined and utilized in the computation of test values.

Tubes are internally coated at one end with anticoagulants and at the other, with controlled amounts of Acridine Orange (to stain the white cells and platelets) and Potassium Oxalate. The Potassium Oxalate, by osmotically removing water from the red cells, increases their density. Otherwise, the nearly similar densities of granulocytes and young red cells (including reticulocytes) could cause intermingling of these cells at their interfacing boundary.

A closure and an insertable plastic float are supplied with each QBC tube. The float settles within the buffy coat during centrifugation, axially expanding the stained white cell and platelet layers by a factor of 10.

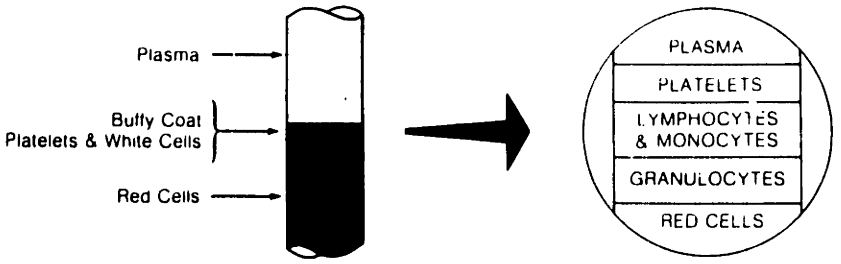


Figure 1. Section of Typical Spun Microhematocrit Tube, Indicating Relative Densities of the Formed Blood Elements.

INTRODUCTION (Continued)

In the QBC Reader the blood tube is illuminated by blue-violet light. Interfaces or boundaries between dark and light red-cell layers and between differentially fluorescing layers of granulocytes, lymphocytes/monocytes and platelets become clearly visible under the microscope of the Reader (Figure 2).

By means of an external knob, the operator can sequentially align the cell interfaces and plasma level (a total of seven) with a stationary cursor in the microscope viewer. Inputs on interface locations are supplied to the microprocessor of the Reader via an "ENTER" switch, pressed each time an interface has been aligned with the cursor. Packed cell volumes and test values are then automatically computed from the six lengths (L_1 through L_6) shown in Figure 3.

Hemoglobin is derived from known and measured forces affecting float depth in the red cells from which red cell density is computed. The latter quantity is then multiplied by hematocrit to yield the hemoglobin concentration.

Test values are displayed by the Reader after the 7th or last interface is entered.

Reagents

Each QBC Capillary-Blood Tube is internally coated with Acridine Orange, Potassium Oxalate, Sodium Heparin, K_2EDTA, Agglutinating Agent and Stabilizers. (See label on blood tube vial for concentrations.)

Warnings and Precautions

- QBC Capillary-Blood Tubes are intended for In Vitro Diagnostic Use.

WARNING

ACRIDINE ORANGE REAGENT MAY BE TOXIC. DO NOT INGEST. AVOID CONTACT WITH SKIN, EYES AND CLOTHING.

- Blood tubes in this pack must be used only with capillary blood.
- QBC tests must be performed in an ambient temperature of 68° to 90°F (20° to 32°C).
- QBC blood tubes are designed exclusively for testing in a QBC Reader. Hematocrit or cell count values from spun QBC blood tubes cannot be obtained on mechanical tube-reading devices or from direct-reading scales.

Stability and Storage of QBC Tubes

KEEP QBC TUBES TIGHTLY STOPPERED IN THEIR OPAQUE GLASS VIAL WHEN NOT IN USE. Remove tubes one by one as needed. Be sure to re-stopper the vial each time. Do NOT remove the strip of desiccant from the vial of tubes.

- Storage

  Store QBC tubes in their sealed vial in a dark, dry place at 60° to 90°F (16° to 32°C). Protect from moisture, direct light and heat.

CAUTION

EXPOSURE TO EXCESSIVE HUMIDITY, LIGHT AND HEAT CAN CAUSE THE COATING REAGENTS IN QBC TUBES TO DETERIORATE

- Stability

  Unopened Vial Expiration: This printed date on the vial label applies only to tubes in the **unopened** vial. See instruction on "Opened Vial Expiration" below.

  Opened Vial Expiration: Tubes can be used for **30 days** after first opening the vial. Record the opening date of the vial in the space provided on the label. Do NOT use QBC tubes after 30 days from opening.

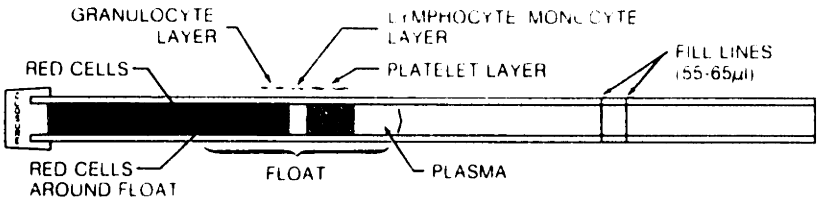


Figure 2. Spun QBC Capillary-Blood Tube, Showing Differentiated Packed Cell Layers.

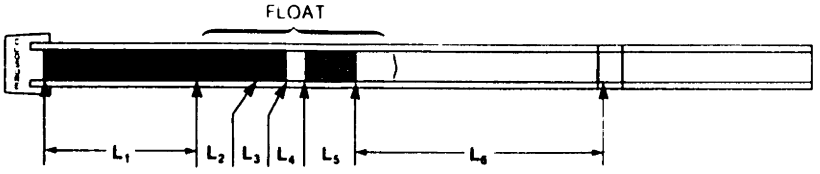


Figure 3. Packed Cell Lengths Used in the Computation of HCT and WBC, GRAN, LYMPH/MONO, and PLT Counts.

SPECIMEN COLLECTION

Specimen Collection and Preparation For Analysis

WARNING

BLOOD SPECIMENS MAY CONTAIN THE HEPATITIS B VIRUS OR HUMAN IMMUNODEFICIENCY VIRUS (HIV). TREAT BLOOD SPECIMENS AS POTENTIAL BIOHAZARDS CAPABLE OF TRANSMITTING INFECTION. ALWAYS USE PROTECTIVE LABORATORY GLOVES WHEN HANDLING BLOOD.

Capillary Blood Collection

Capillary blood should be collected from a finger puncture directly into the QBC tube, according to techniques described under TEST PROCEDURES. Blood from the plantar surface of the heel or other skin areas is NOT recommended. To avoid sampling errors, the blood must be free-flowing and collected with minimum delay. Carefully observe the following blood collection procedures and precautions:

1. The finger to be punctured must not be cyanotic or edematous. If cyanotic or cold, immerse in warm water (30°C to 40°C) for 3 to 5 minutes before puncture or use a moist compress or warm pack.
2. Clean the finger area with an antiseptic agent and wipe dry.
3. Puncture the finger with a sterile lancet, wipe away the first drop of blood, and collect the next drop or two. Specimens taken after the first several drops may yield lower counts, since platelets may adhere to the wound site or may aggregate in the blood drop.
4. Slight pressure may be applied some distance from the finger puncture. Avoid squeezing the puncture area as it may cause dilution of the blood with tissue fluid.

Anticoagulants

QBC Capillary-Blood Tubes are internally pre-coated with sodium heparin and di-potassium EDTA.

Interfering Substances

- Bilirubin: No effects on QBC test results have been observed at bilirubin concentrations up to 8.5 mg/dl.[8]
- Coumadin: Coumadin anticoagulant therapy has no clinically significant effect on QBC test results.[8]
- Doxorubicin: Treatment with the anthracyclic drug Doxorubicin does not appear to interfere with QBC test results.[8]
- Other Drugs: The effects of other potentially interfering drugs and their metabolites[9] on QBC test results have not yet been established.

Stability of Filled Blood Tube

Filled blood tubes should be prepared and centrifuged promptly after blood collection. Consult "Assay Timing" in the TEST PROCEDURES Section for additional details.

TEST PROCEDURES

Materials Provided

The items below are supplied in the Catalog No. 4241 tube pack.

- 100 QBC Capillary-Blood Tubes;
- Tube Closures and Floats (100 ea);
- Package Insert.

Note: QBC tubes and floats are matched by production lot to yield optimum performance. To insure this optimum performance, it is recommended that leftover tubes or floats from this pack not be used with parts from other packs **with different lot numbers**.

Materials Required, But Not Provided

A Becton Dickinson QBC Reader System is required for testing QBC Capillary-Blood Tubes.

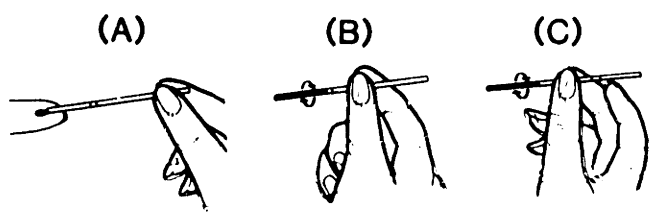
For blood tube preparation, each QBC Reader System is supplied with a Centrifuge, Work Station Organizer. With the **Model No. 4200 QBC Reader only**, a 43° C Incubator is included for warming the blood tubes prior to centrifugation. Incubation of blood tubes at 43° C is NOT required when testing with other Reader models due to modifications in their electro-optical components.

Pre-Test Conditions

- Reader ON and warmed for at least 5 minutes, and "CAP" (capillary) mode activated.
- QBC Tube Tray placed in holder of Work Station. (Note: For easy removal of tray cover, pry up cover at one corner; save cover for re-use.) Because QBC tubes are light-sensitive, remove the blood tubes individually from their vial as needed.
- **With Model No. 4200 QBC System Only:** Incubator ON and warmed for at least 15 minutes.

Procedure Steps

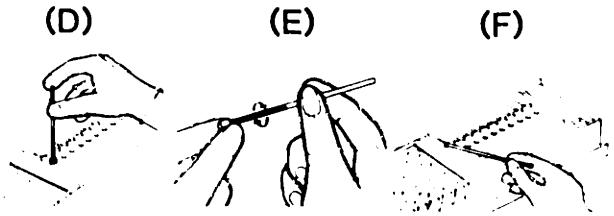
1. FILL AND MIX TUBE



Fill the tube with finger puncture blood at the end nearest the two black lines (A) to a level between the lines. With lint-free tissue wipe any blood on the outside of the tube,

being careful not to draw any specimen from the tip of the tube. Keeping the tube nearly horizontal, roll the tube between the fingers several times to mix the blood and anticoagulants (B). Turn the tube around and tilt, allowing the blood to flow to the opposite end of the tube (C). Roll the tube between the fingers **at least 10 times or for at least 5 seconds** to mix the blood with the coating of Potassium Oxalate and Acridine Orange. PROCEED IMMEDIATELY TO STEP 2.

2. SEAL TUBE AND INSERT FLOAT



Place the index finger over the end of the tube nearest the fill lines, and insert the distal end into a Closure in the tube tray (D). MANUALLY TWIST AND PUSH THE CLOSURE ONTO THE TUBE TO FORM A LEAK-TIGHT SEAL (E). BE SURE THE CLOSURE IS ON STRAIGHT. FAILURE TO SEAT THE CLOSURE STRAIGHT MAY RESULT IN BLURRED INTERFACES. Slide the unsealed end of the tube over the tip of the pre-positioned float (F) and push until the float is as far as possible inside the Tube. Gently lift the closure end of the Tube until the float releases from its tray slot. Raise the unsealed end of the tube slightly above horizontal to prevent the float from falling out. If necessary, press the float against a clean surface to push the end into the Tube.

NOTE: NEVER TOUCH FLOATS WITH THE FINGERS. Use the forceps supplied with the Reader.

Promptly proceed to Step 3 or Step 4.

3. **(WITH MODEL 4200 QBC READER ONLY)** — INCUBATE FOR 5 MINUTES

Insert the Tube, unsealed end first, into a well of the QBC Incubator and set the timer dial for 5 minutes. When the timer bell rings, PROMPTLY REMOVE THE TUBE FROM THE INCUBATOR. CENTRIFUGE IMMEDIATELY.

4. CENTRIFUGE FOR 5 MINUTES

Place the QBC Tube(s) on the rotor of the Centrifuge according to procedures in the applicable Operator's Manual. If an odd number of tubes are being centrifuged at one time, use any empty Tube (with closure and float) for balancing. Secure the head cover and press the centrifuge lid down until it latches. Centrifuge for 5 minutes according to instructions in the applicable Operator's Manual.

PROMPTLY REMOVE THE TUBES FROM THE CENTRIFUGE.

CAUTION

- Excessive heat may disturb cell layer interfaces in the centrifuged blood tube. Avoid picking up or handling the spun tubes below the plasma column or placing them on warm surfaces or under intense light.
- Do not twist or move the closure after centrifugation.
- If not read immediately, tubes must be removed from the centrifuge and stored in a vertical, closure-down position to maintain cell layer boundaries (see below).

Centrifuged tubes are stable for up to **4 hours prior to reading,** provided they are stored vertically (closure down) away from heat and direct light. Slots for storing the tubes are provided on the QBC Work Station.

5. READ LAYER LENGTHS AND RECORD TEST VALUES

Insert the centrifuged tube into the QBC Reader according to directions in the applicable Operator's Manual. Be sure the Reader is in the "CAP" mode. Read the 7 interfaces in the QBC capillary tube, then record all test values as directed in the Operator's Manual. Note: Since cell interfaces may become slightly blurred from prolonged exposure to heat, read QBC blood tubes as soon as possible after inserting in the Reader.

Assay Timing (Blood Tube Stability)

To accommodate individual lab routines and to permit batch testing, between-step delays can be made in the tube preparation procedures. QBC test results will not be affected, provided the following times are not exceeded:

- After filling, mixing, sealing and inserting the float (end of Step 2), tubes should be centrifuged as soon as possible. However, not more than 20 minutes should elapse between insertion of the float and completion of centrifugation.
- From Completion of Centrifugation (Step 4) to Tube Reading . . . 4 hours, provided tubes are stored in a vertical closure-down position.

Test Note

If problems are experienced with the color of cell layers or the readability of any interface, refer to the applicable Operator's Manual.

Calibration and Quality Control

Test results obtained by the QBC method should be compared periodically with results obtained by other methods. The following reference procedures are recommended.

Parameter	**Ref. Method**
HCT	Centrifuged Microhematocrit
HB	Cyanmethemoglobin Method
WBC	Impedance Cell Counter
Gran	100-Cell Manual Differential
Lymph/Mono	100-Cell Manual Differential
Platelet Count	Phase Microscopy or Impedance Cell Counter

A daily pre-test calibration check of the QBC Reader is recommended with the Capillary Calibration Check Tube supplied with the Reader. Procedures are fully described in the applicable Operator's Manual.

Test Results

Test values displayed by the QBC Readers are presented in the following digital/decimal format.

Hematocrit (%)	XX X
Hemoglobin (g/dL)	XX X
Platelet Count (x 10^9/L)	XXX
White Cell Count (x 10^9/L)	XX X
Gran (%)	XX
Lymph/Mono (%)	XX
Gran (x 10^9/L)*	XX X
Lymph/Mono (x 10^9/L)*	XX X

*To compute the number of Granulocytes and number of Lymphocytes/Monocytes when testing with the **Model No. 4200 QBC Reader**, multiply the percent values of the parameters by the WBC.

When irregularities are detected in layer length measurements or in tube reading techniques, the Reader will automatically display an alphanumeric Alert Flag and the test will be aborted. In such cases, no test results (or partial results) will be displayed. Consult the applicable Operator's Manual for a description of Alert Flags.

Limitations

1. The hematologic parameters measured by the QBC method are valid over the following range of values.

Hematocrit	25-55%
Hemoglobin	5-20 g/dL
Platelet Count	80-600 (x 10^9/L)
White Cell Count	2.0 - 30.0 (x 10^9/L)
Gran	1 - 99%; 0.02 - 29.7 x 10^9/L cells (over a WBC of 2.0 - 30.0 x 10^9/L)
Lymph/Mono	1 - 99%; 0.02 - 29.7 x 10^9/L cells (over a WBC of 2.0 - 30.0 x 10^9/L)

   If the specimen yields values outside these ranges, results should be confirmed by alternate methods.

   QBC Granulocyte and Lymphocyte/Monocyte counts are not intended to replace the conventional manual differential white cell count. Some disease states are characterized by the presence of abnormal white cell types and yet may display normal quantitative relationships of Granulocytes to Lymphocytes/Monocytes. Due to grouping of the white cell subpopulations, the QBC method cannot discriminate between normal and abnormal cell types and may not indicate the presence of disease states where the number of certain white cell types may be abnormal (e.g., eosinophilia).

2. QBC tests must always be performed in a temperature environment of 68° to 90°F (20° to 32°C). If blood tubes are tested at temperatures below 68°F (20°C), results may be erroneously high; if tested above 90°F (32°C), interfaces in the blood tube may become blurred and unreadable.

3. VALUES CANNOT BE OBTAINED BY THE QBC METHOD WHEN DISTINCT CELL LAYERS AND WELL-DEFINED INTERFACES FAIL TO FORM IN THE CENTRIFUGED BLOOD TUBE. Note: Non-separation or cell "streaming" can occur under certain hematologic or pathologic conditions, e.g., when an orange-yellow layer of granulocytes fails to form, or the lower boundary is so poorly defined that a clear interface cannot be identified. The condition is generally the result of a shift in red-cell specific gravity toward that of the granulocytic leukocytes, causing the red cells and granulocytes to intermingle.

4. Certain drugs may affect the accuracy of QBC test results. (See INTERFERING SUBSTANCES.)

Expected Values

The means and ranges listed in the following table were determined by the QBC method with capillary specimens from adult donors working in an industrial environment.

EXPECTED VALUES
QBC CENTRIFUGAL HEMATOLOGY PARAMETERS[8]
(Capillary Test)

Mean Value Parameter		Mean Value	Range (± 2 S.D.)
HCT (%)	Males	43.3	35.4- 51.2
	Females	40.7	34.7- 46.6
PLT (x 10^9/L)		261	124 -399
WBC (x 10^9/L)		7.3	3.7- 10.9
GRAN (%)		64.8	50.6- 79.1
GRAN (x 10^9/L)		4.5	2.2- 6.9
LYMPH/MONO (%)		35.1	20.9- 49.4
LYMPH/MONO (x 10^9/L)		2.4	1.2- 3.5

Normal hemoglobin ranges obtained on applicable QBC Readers should be virtually identical to the following normal ranges reported in the literature:[2]

Adult Males: 14-18 g/dL
Adult Females: 12-16 g/dL

In accordance with good laboratory practice, each laboratory should develop normal values based upon the geographical area, age, sex, and other factors specific to the population being tested.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision (Within-Run Reproducibility)

	MEAN VALUE	MEAN C.V. (%)
HCT (%)	40.6	2.29
HB (g/dL)	12.7	1.5
PLT (10^9/L)	262	11.67
WBC (10^9/L)	6.6	8.25
GRAN (%)*	64.2	6.46
GRAN (10^9/L)	3.5	7.4
LYMPH/MONO (10^9/L)	2.2	14.9

*QBC Percent Granulocytes and Percent Lymphocytes/Monocytes always total 100%. Therefore standard deviations for percent Granulocytes and percent Lymphocytes/Monocytes are identical.

Accuracy

Graphs and statistical data on the correlation of QBC Capillary Blood Parameters with those of reference methods are shown in Figures 4-11.

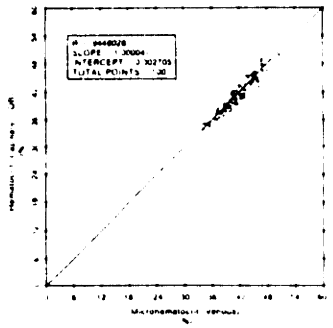


Figure 4. Capillary Blood Correlation: QBC Hematocrit vs Microhematocrit Reference Method.

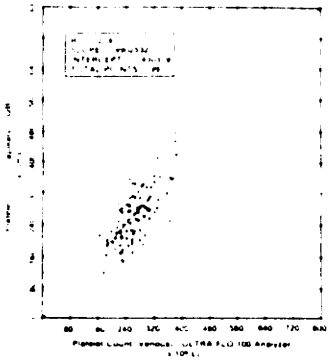


Figure 5. Capillary Blood Correlation: QBC Platelet Count vs ULTRA-FLO 100 Platelet Analyzer Counts.

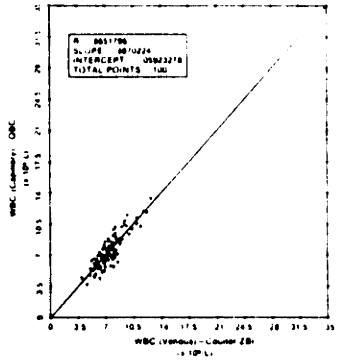


Figure 6. Capillary Blood Correlation: QBC White Cell Count vs Coulter ZBI White Cell Counts.

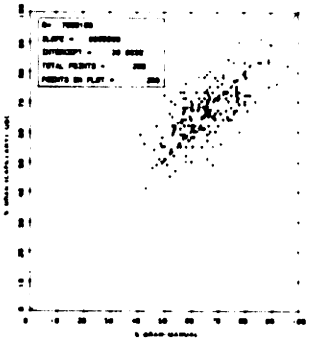


Figure 7. Capillary Blood Correlation: QBC % Granulocytes vs 100-Cell Manual Differential.

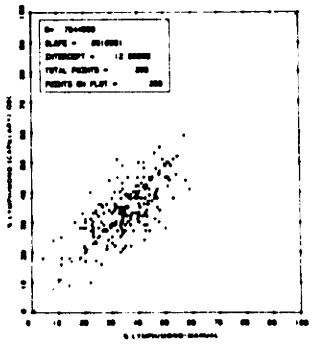


Figure 8. Capillary Blood Correlation: QBC % Lymph/ Mono vs 100-Cell Manual Differential.

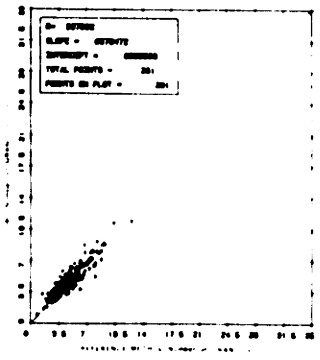


Figure 9. Capillary Blood Correlation: QBC Granulocyte Count vs Reference Manual Count.

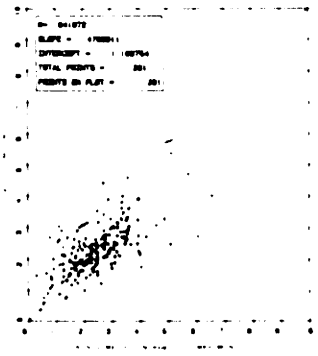


Figure 10. Capillary Blood Correlation: QBC Lymphocyte Monocyte Count vs Reference Manual Count.

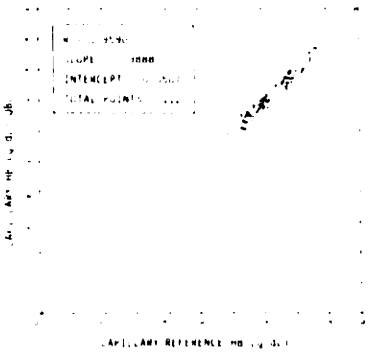


Figure 11. Capillary Blood Correlation: QBC Hemoglobin vs Cyanmethemoglobin Method.

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11. National Committee for Clinical Laboratory Standards (NCCLS): Approved Standard H15-A (1985) "Reference Procedure for Quantitative Determination of Hemoglobin in Blood."

Ordering Information

QBC Tubes for Capillary Blood: Package of 10 Trays — 10 Tubes, Floats & Closures per Tray — **Reorder No. 4241**.

Becton Dickinson
Primary Care Diagnostics
One Becton Drive
Franklin Lakes, N.J. 07417-1882

INTRODUCING

FIBRINOGEN FOR QBC AUTOREAD & REFERENCE OWNERS

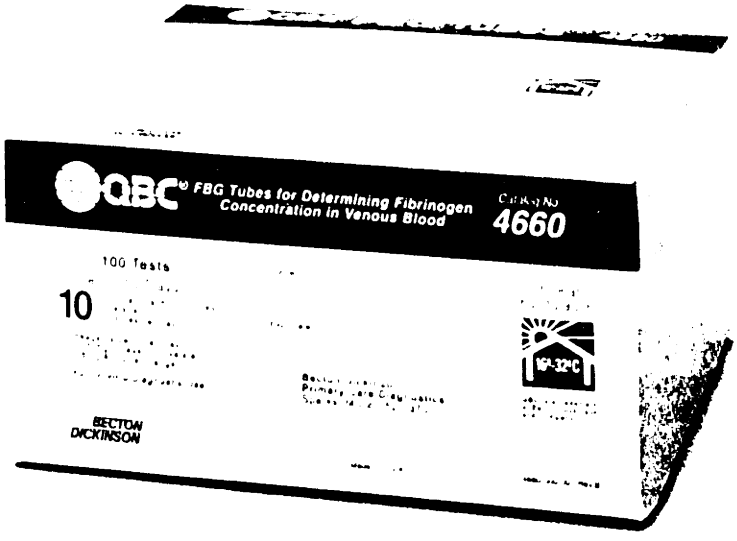
ELEVATED PLASMA FIBRINOGEN IS AN IMPORTANT RISK FACTOR FOR CORONARY HEART DISEASE

- [illegible]

- [illegible]

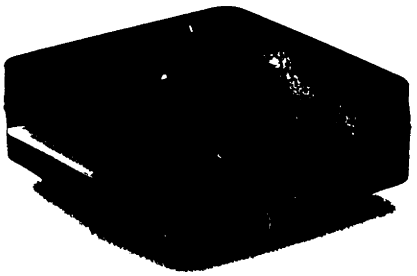
- [illegible]

NEW! QBC FIBRINOGEN



BECTON DICKINSON

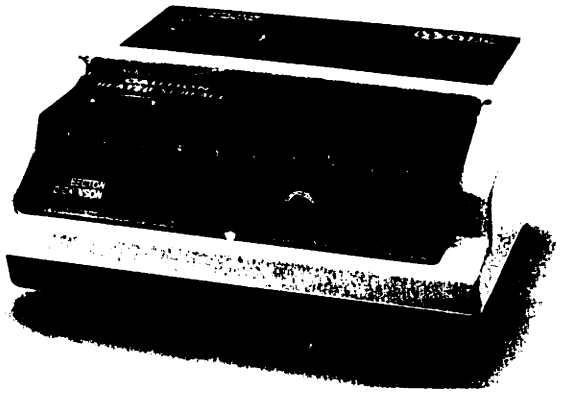
ADDITIONAL ITEMS NEEDED FOR FIBRINOGEN TESTING.



SOFTWARE UPGRADE

Plug in cartridge contains software for all standard QBC hematology parameters as well as software for computing and reporting Fibrinogen values. Upgrade can be performed on-site by customer.

Cat. #4286



QBC INCUBATOR

The QBC Incubator is designed for ease of use featuring easy loading and pre-set thermostat to automatically heat Fibrinogen blood tubes to the correct temperature necessary for testing.

Cat. #4302

QBC BLOOD TUBES

Easy to use QBC blood tubes are specially designed for the quantitative determination of Fibrinogen.

Cat. #4660

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1. *All AUTOREAD customers after July 1, 1992 will automatically have Fibrinogen software.*
2. *Current AUTOREAD and Reference customers can easily upgrade to new software.*
3. *All others (QBC II, QBC II Plus, QBC I, and QBC+) will need to trade up -- Attractive Trade In Values Will Be Offered.*

ASK YOUR DISTRIBUTOR REPRESENTATIVE FOR DETAILS OR CALL 1 800 631-8064

Appendix B: Project Schedule

This section provides an overview of the project timetable. I have broken down the timetable to major tasks in engineering and market research. During the product development cycle, both engineering and market research worked concurrently. The human interface aspects were also considered simultaneously during the process. The details of the human interface design can be found in Mark Driscoll's and Nanette Palmer's mechanical engineering bachelor's theses.

Engineering	**Market Research**
concept generation:: 2 months	*experiential interviews*: 1 month
sub-system concept selection:: 2 months	*focus group participation* : 1 week *card-sort interviews:* 1.5 months *house of quality*: 1 month
system selection:: 2 months	*conjoint analysis*: 4 months
breadboarding: 3 months	
developing a prototype: 7 months	

Appendix C

C1. Focus Group Guide & Results

Moderator's Guide
February 10, 1992
Hematology Instruments

I. Introduction (15 minutes)

- Moderator
- Focus Group Technique
- Participants (Name, title, function, existing equipment, lab operation)

II. Identifying Needs (100 minutes)

A. I would like to imagine that this group is the design team for the next generation of hematology instruments designed for operations specifically like yours. I will simply act as chairperson of the committee but you will come up with the ideas.

B. To start, I would like you to discuss the general areas of concern or possible improvement. Having established that list, then we will brainstorm within each major category. Please note that we don't have to solve all the problems tonight. However, I would like to clearly understand what unmet needs exist among you and your peers.

C. Let's get started. What are the key issues, concerns, and design features we should discuss when designing the ideal hematology instrument? Think about your existing equipment and what types of frustrations you have, what constraints you hit, what seems to work very well, etc...

Probes will be offered after the group is finished:

- Walkaway Capability
- Throughput
- Sample Handling (including safety)
- Size
- Reliability/Maintenance
- Menu Choices (desired functions)
- Data Management / Interface Capability
- Cost (capital and operation)
- Patient I.D.
- Accuracy
- Ease of Use / Training

Now that we have identified the major categories, let's go through each one and specifically define the dimensions of the needs/possible areas of improvement.

III. Wrap-up (5 minutes)
A. The moderator will return to the observation room for any final questions, probes, etc. and adjourn the session.
Estimated Interview Time: 120 Minutes

C2. Customer concerns and requirements

SIZE

- Breadbox
- Lighter/Thinner
- Big enough to work on

MAINTENANCE

- Self Cleaning
- Design for Maintenance
- Color Coding of Tubes
- Contamination
- Filters
- Easy Access
- Manuals
- Safety

SPEED

- Sequence of Processing
- < 30 seconds per sample

SAMPLE HANDLING

- Automatic
- Repeat Test
- Minimize Specimen Quantity
- Patient ID
- No Opening Tubes
- Clot Detector
- Disposal
- Walkaway

DISADVANTAGES OF PATIENT ID

- Small Labels
- Matching
- Smearing

DATA MANAGEMENT

- Complete interface capability with other lab machines (eg/ chemical analyzers)
- Put on Disk
- On Board Maintenance S/W
- Low Reagent Warning
- Hold QC Data
- Paperless
- Store 2 Days Worth of Results

MENU

- Reticulocyte Counts
- Spin a Smear
- Total Eosinophils
- 5 Part Differentials
- Sedimentation Rate
- Fluid Counts
- Better Automated Differentials
- RDW (red cell distribution width)

DISADVANTAGES OF REAGENTS

- Bulky
- Hard to Open
- Uses Alot
- Short Shelf Life
- Low Container
- Toxic
- Expensive
- Gets Contaminated
- Sediment Crusts
- Lots of Waste

OVERALL SYSTEM

- Quality Control
- Longer Expiration Date on Reagent
- Easy Calibration
- Replaceable Caps
- Covers Hi-Tech Looking
- Can Hook Up on Both Sides
- Low Cost
- Less Reagent Waste
- Safety
- Quieter
- Less Tubing
- Modularity

Table C1. Customer Voices from the Focus Group

C3. Card-Sort Interviews

A list of 61 customer needs were identified by Richard Wong after the focus group session (see table below).[43] Care was taken to preserve the voice of the customer so that translation of customer requirements to engineering design requirements (House of Quality) can be made without losing information. This list was used in card-sort interviews to determine the relative importance of each customer need. These results have been incorporated into the House of Quality (described in detail in the next section). A typical card-sort interview methodology is as follows:

1. Transcribe each of the customer needs on cards before the interview.
2. During the interview, spread cards out on a large table.
3. Have the customer sort the cards according to their own categorization scheme.
4. Have the customer rank the categories according to relative importance.
5. In each category, have the customer rank the cards in the order of relative importance.
6. Use these ranking results to develop a relative importance of each customer need.[44]

1) Machine is durable enough to last over 5 years
2) Achieves level of accuracy equivalent to Coulter STKR.
3) Analysis CBC time less than a minute
4) Needs to print out report quickly
5) No opening sample tubes
6) Reads data and determines whether automatic repeat of abnormals necessary
7) Performs repeat test automatically
8) Able to load batches of tests at once, not in sequence
9) Batch capabilities of 1 to 100
10) Machine that can be stopped for a RUSH job or emergency CBC.
11) Feed information into my lab system automatically
12) Can handle more than one type of tube for automatic sampling
13) Low sample volumes for automatic testing
14) Able to throw specimens in cassettes, hit a button, and walk away
15) Eliminate opening tubes to solve aerosol problem
16) Eliminates need to handle waste
17) Eliminates need to wipe aspirator tip
18) System that eliminates human error in patient ID
19) Accuracy even if the blood clots
20) Eliminates the problem of machine jamming with blood clotting
21) Hematology analyzers the size of bread boxes
22) Able to reach tops of instruments
23) Instrument light enough to carry
24) Machine quiet enough, so you can talk on the phone next to it.
25) Uses little reagent and tubing
26) Extension cables for plotters and data terminals
27) Machine covers that are easy to remove
28) Machine automatically turns off when cover is removed
29) Machine looks really high-tech
30) Message center is located next to location where sample is loaded
31) Results that are flagged when abnormal results come up
32) Aspirating tip or metal probe that isn't going to snap off or be damaged
33) Not spending a lot of time getting machine started up
34) Equipment cleans and bleaches itself
35) Reagent that doesn't crust up
36) Having a low reagent warning
37) Elimination of reagent
38) Elimination of daily maintenance
39) Elimination of weekly maintenance

40) Elimination of monthly or long-term maintenance
41) Machine that's easier to take apart and put back together
42) Color coded tubes that identifies where they're supposed to go inside the machine
43) Simplified manuals with pictures and directions
44) Complete interface capability to information system
45) Able to store QC information
46) On-board maintenance software that tells what the problem is and how to fix it
47) Eliminating error codes and using words that tell you what's wrong.
48) Able to store test information
49) Ability to interpret QC information and recognize drift
50) Push button for recalibration
51) System under $100K
52) 24-hour service contract available
53) Internal modem with communications software for sending info.
54) Battery operated hematology instrument
55) Machine that fits on a mobile stand
56) Contains alternate technology for backup testing
57) Can automatically make a smear if automatic test fails
58) Capability to store information on disks
59) Format of results can be customized
60) System includes on-line manuals for training
61) Instrument with fully integrated personal computer

Table C2. 61 Customer needs identified from the focus group

We realized that medical technicians' time was precious so we tried hard to expedite card-sort interviews without undermining thoroughness. But, from my experiences, the medical technicians were rather willing to take the extra time and effort to provide their best judgements on categorizing and ranking the various customer requirements. I was able to ask various questions to clarify ambiguous issues that came up during brainstoming sessions and also to observe the customers' laboratories, hematology machines, and their daily practices.

Appendix D: Brainstormed Raw Data

D1. Failure Modes and Effects Analysis

Failure modes and effects analysis (FMEA) is used during product development stages to design for safety, preventive maintenance, preventing potential failures, and troubleshooting. FMEA considers failure modes, failure effects, failure causes, severity level, detection level, occurrence level, and recommended action (Figure D1). A *failure mode* points out how a failure happened. A *failure effect* explains the outcome resulting from a failure. A *failure cause* describes the reason for a failure. *Failure severity level* is a relative number that provides a means of assessing the severity of a failure. *Failure detection level* is a relative number to estimate how well a failure can be detected. *Failure occurrence level* is also a relative number to estimate how often a particular failure would occur. Finally, recommended action provides a guideline to allow the service technician or machine operator to correct a failure. These components of FMEA help to eliminate avoidable failures during the design phase, design for preventive maintenance, and most importantly assist to design a highly reliable product.

During the initial concept generation phase, our team spent a couple of brainstorming sessions generating potential failures of the QBC® Walkaway system. Table D1 shows the results thusfar. It is suggested to complete the "recommended actions" and severity, detection, and occurrence level to help considering maintenance and reliability issues with the Walkaway system.

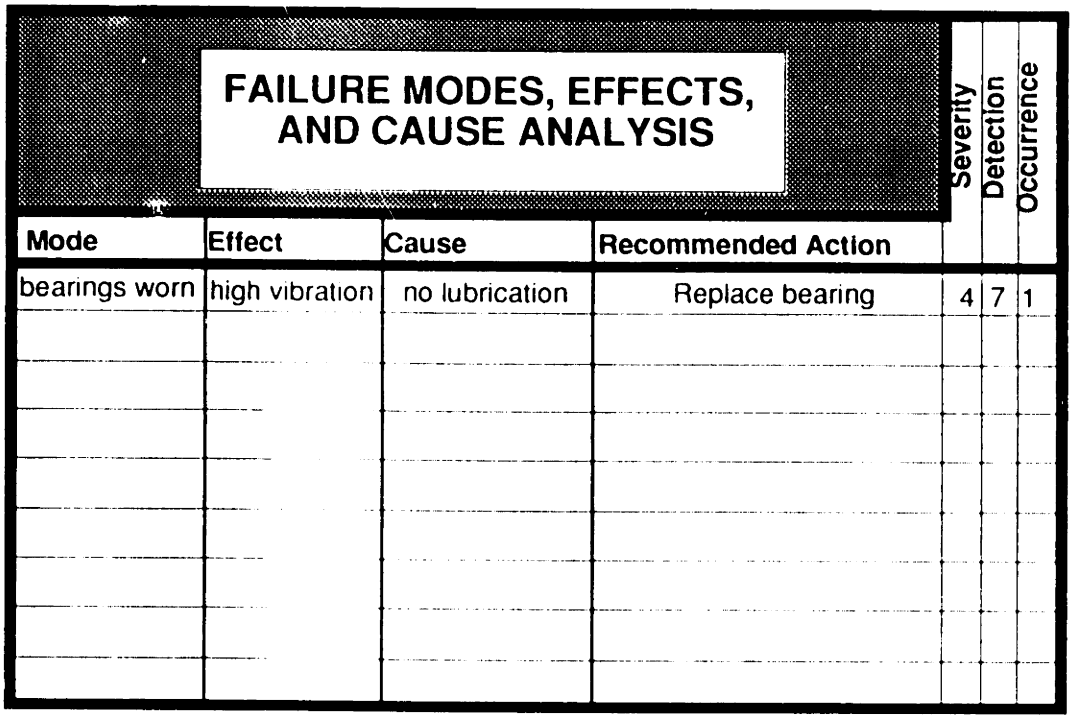


Figure D1. Sample FMEA Chart

Failure Mode	Effects	Cause
• optical reader does not read	blood clots in tube	improper phlebotomy
	layers don't separate, can't make accurate reading	no anti-coagulant in tube
	tube indexer won't rotate tube	power goes out while processing samples
		optical system is unfocused
		no float in blood tube
		optical light sources burn out
		dirt or scratches on the outside or inside of tube
• rotor is unbalanced	machine walks	rotor bearings worn
	rotor wobbles when spinning	improper tube loading
	too loud or noisy	improper manufacturing control
	centrifuge speed leaves acceptable range	
	rotor flies off	
	rotor doesn't get up to speed	
	machine is not placed on level surface	
	motor runs very hot	

• centrifuge does not start	nothing happens	power failure
		machine cover not closed
		rotor cover jammed
		motors burned out
		bearings locked up
• accidental access to rotor during spinning	rotor flies off	operator receives wrong information
	machine stops reading and centrifuging	cover lock sensor failure
• actuators lock up	tubes and/or carousels don't move	dirt in mechanisms
	a sequence of events cannot be interrupted	worn bearings
	material handling system jams	loose electrical connections
	sensor failure	
	redundant sensor failure	
• display malfunctions	nothing is visible	power failure
	display shows wrong numbers	key pad failure
• blood is spilled	spilled blood in rotor and carousel	tube is missing a cap
	HIV infection	tube inserted backwards
	electronics become contaminated with blood	tube breaks during centrifuging
	tubes overflowing with blood	
	aerosols are created	
•computer system malfunction	decisions cannot be reversed in user interface	wrong language is displaced
	patient identification gets mixed up	software bug
	patients get wrong diagnosis	EPROM is erased
	rotor spins for wrong amount of time	sensor failures

Table D1. Preliminary Results of FMEA

D2. Preliminary Brainstormed Sub-System Ideas

Display CBC information

1	interface to external terminal and have it display the information
2	similar display on a connected PC as the hardware display
3	use friendly pop up windows
4	mouse driven
5	icon driven, click on pictures that make sense using mouse
6	default driven routine which you could interrupt
7	display tube picture and associate numbers with the tube
8	use a pie chart to display blood content
9	bar chart indexed to a reference that might be a dynamic reference which is good/bad
10	line graph display of cell size like Coulter
11	buttons shaped like tube layers, press one to get that layer's info
12	menu of parameters select one that highlights, get more information
13	calculator print out
14	built in overhead projector
15	paper perforated, half goes to doctor, half to patient
16	monochrome monitor TV screen
17	display card
18	stickers that you print onto
19	color of document is a code
20	wireless radio link between machine and doctor's computer
21	put the printer in each office, route data to printers
22	relevant QBC data goes to office, technical into stays in lab
23	feed back on buttons, beeps or turns on/flashes a light
24	preferences for display, sound control, light, menus, etc
25	modular, you can add features to the display system
26	displays in any language or is a language independent system
27	configurable output forms and/or screen
28	computer ink jet/dot matrix printer
29	LCD display screen: small and scrolling or large with all of the data at once
30	lap top flip up screen
31	adding machine print out on stickers then stick to a patient form
32	pre-made forms or prints form with the data
33	adding machine print out on stickers then stick to a patient form
34	store all info on a magnetic strip then stick into a reader that plays the info back
35	touch screen for operation
36	screen buttons with mouse/cursor keys/track ball to select
37	take picture and display picture of the bands wirh the data next to it
38	analog meters for the cell counts
39	graphical output like bars or like the acceptable range print out on the Autoreader

40	color ink jet printer
41	sound based coding like the urine test on TV
42	voice output of the data
43	physical bars like on a stereo and the acceptable range could be color coded
44	check printer slot that you put the patient form into and press a button; print number's and names on the form; Or, bar code sticker on the form that is also on the tube; computer only prints if they match.
45	auto feed pre-printed forms like a copier/laser printer
46	laser printer
47	VCR-like graphical LCD display
48	oscilloscope display of the raw data

Cell Separation

1	change the cross section of float to let blood fo by easier
2	shape float like a missile to let stuff by
3	continuous rotor, add and remove tubes dynamically, keep track of each tubes time
4	synchronizer: have second rotor that gets tube up to speed and transfers to the full time rotor
5	have multiple rotors that accept tubes and clutch onto rotor
6	have multiple centrifuges that feed the same reader
7	square machine with rotors at corners with reader in the middle
8	multiple mini/super mini machines that take samples
9	modular system that accepts more centrifuges if the practice needs the volume
10	centrifuge tray is the tray that comes to machine for routine large batches
11	4 or 6 bar linkages that provides constant acceleration
12	add some fluid that deosn't case cells to rupture so centrifuge can go faster
13	add fluid that reduces viscosity, maybe dilution with a safe liquid
14	a few tubes spun at a very sharp angle makes centrifuge smaller
15	put blood at the top of the tube it separates faster if it goes in one direction
16	use magnetic field with magnetic additive to speed up separation
17	centrifuge to get vertical layers then let slide into horizontal layers
18	flow sorter: "electron gun"
19	beckman JE-6B eutinator system
20	put a vacuum on to allow you to speed up and not crush cells
21	speed up gradually to allow delicate cells to go to center where the force is lower allowing you to go faster
22	chemicals to make the cell stronger so you can go faster
23	dilute with a liquid to make separation happen faster, might be a gradient density liquid
24	add the float after centrifuging
25	centrifuge in a centrifuge optimal tube tube then transfer to a float tube
26	unit gravity sedimentation, it separates lymphocytes and monocytes
27	use chromotography
28	coil planet centrifuge
29	self balancing rotor
30	front clip go hold tube in place on rotor
31	centrifuge 1, 20, 40, 100 tubes at a time
32	put all tubes in one holder and use a counter weight
33	push sieves down through the tube
34	linear acceleration and deceleration
35	high speed reciprocating arc motion
36	orient the tray vertically
37	ferris wheel mounting of tubes in a vertical tray
38	spin horizontally and read vertically
39	spin around its center, get two samples giving two sets of data one could have a float and one could not
40	tag cells wirh polar and non-polar liquids to cause organic layer separation

41	spin on the tubes axis and in a cetrigue to get wider bands and read while it is spinning
42	centrifuge at the magic angle
43	heat while spinning to speed up separation
44	centrifuge half way then stick the float in
45	get a macro separation wirh a chemical, stick the float in, and spin
46	increase the speed and decrease the radius of the centrifuge
47	use multiple platter of tubes
48	winged centrifuge
49	use an electric field to separate by charges
50	vibration separation like a shaker
51	vibration while centrifuging that is not necessarily continuous
52	tage cells with a magnetic material and use magnets to separate
53	make the tube bigger to increase separation rate
54	vibrate tray up and down during centrifugation

Measuring float and tube annulus

1	LVDT with scissors measures ID of tube and OD of float
2	make the tube huge and measure with a ruler
3	angled test tube with a laser and an array to measure laser reflection
4	laser across diameter of the tube end at an angle. use laser dot and measure the dots intensity on the other side
5	measure the features of a diffraction pattern
6	fiber optic concept, total internal reflection to get ID of tube
7	measure back pressure to get the average area of the tube
8	make measurements bsed on pv=nrt
9	laser distance sensors and fiber optics while spinning the tube
10	measure the time for a temperature to diffuse through the tube walls
11	use glass wall as a dielectric and put an electrode inside and out
12	charge the glass and use charge sensor to pick up charges on the inside
13	flying scanning laser dot with one way optical plate and photodiode to measure the tube end
14	refractive index based measurement, measure how much it slants
15	measure reflectance of light off of the center of the tube as it bounces back off each wall
16	use ultrasound instead of a laser to measure echoes
17	fixed volume of a substance to be measured
18	push a piston/damper through at constant velocityand measure force
19	tapered plug at one end, measure how far it pushes in
20	umbrella like scissors in the tube, measure how much it opens
21	scanning dot across the tube with intensity sensor on the back side
22	shadow graph with a ccd or similar sensor on the other side
23	marks on the tube edge that interfere with the tube ID edge that can be measured
24	polarize outside of tube different than inside makes a shadow for the intersection of the two
25	magnetic shadow graph, coat the outside or inside with magnetic material
26	venous pipette gives known amount, measure the height of the blood inside the tube and calculate the average area
27	end to end shadow graph
28	when blood is moving use Doppler ultrasound like HP uses
29	use statistical info on tubes and floats, calc max error
30	measure intensity drop of light from inside of tube to outside
31	put hall effect sensor on one side and magnet on the other side
32	constant annular area from nibs and proportionally compressing float
33	shove a plug of known volume in measure its linear expansion
34	have the machine measure the float then stick it in
35	heat the blood to get a thermal expansion factor
36	expanding float, use heat to expand, ot creates a unform thin layer every time
37	put a rod in and heat in
38	tapered mandrel, conical to measure ID of the tube:go/no-go pins
39	sequence of feeler gages that are concical or just flat to measure gap; if vertical, measure how far the float falls onto the feeler gage

40	blow air through and measure the fluid resistance
41	coat the float with a substance tha can be detached
42	float falls at a velocity that cna be correlated to the area of the annulus
43	measure float velocity while falling in uncentrifuged blood, calculate tolerances based on density
44	change the material of the float so that the tolerances can go up, fix the position of the float or make it longer so it still hits the buffy layer
45	change the float geometry to improve tolerances, ie if a square is easier to manufacture
46	change the float geometry to a different magnification principle, like that of a lens maybe
47	optical magnification built into the float ot the tube
48	manufacture tubes of non-constant diameter to integrate tube and float
49	jam the float in with a hole in the middle and make it transparent, improve tolerances. if opaque, put the hoel down one side
50	tube is flexible and crimp it where the buffy coat ends up
51	longer tube and float to reduce the percent error
52	cylindrical lens effect like a fever thermometer
53	oil slick: interference that creates dark lines that can be measured to get gap
54	light down axis, collect at the other end, correlate to gap size
55	calculate gap size by measuring the weight of each item
56	resonant frequency: tap the tube, measure the vibration frequency and correlate
57	shake back and forth, record the time the float takes to bounce from side-to-side
58	scissors idea
59	quick set gel, put in and let set, pull out and measure dimensions
60	read across the tube to get bands using the current technology
61	measure the flow rate to stop the float from falling
62	bellows plug, pushin and it compresses, measure the volume or pressure change
63	fiber optic light that goes down in the tube
64	opaque float and across axis illumination with a mask to get the gap size by intensity measurement
65	every float is a blown up bellow you expand to the sides and then back off a known amount
66	freeze the tube, cut open, and measure the cross section

Measuring bands

1	correlation, move a band up and when it overlaps another band it will have high correlation
2	have coarse and fine series of sensors that get you to the local areas of interest
3	shaker stack that measures all of the cell sizes
4	cell size forms gradient, measure a few and estimate the distribution of cell sizes
5	optical shadow graph with a detector on the other side
6	zoom way in and detect reflection changes as you scan
7	lens to make tube fat, average around more of tube so that we scan on two sides and never rotate tubes
8	ring of scanners that moces down tube so that tube does not move
9	no moving parts, scanners/sensors that have regions that overlap to get the whole tube in
10	two area scanners at 90 degrees, ligth shines in two directions, sensors are as long as the tube
11	optical correlator, a mask like an LCD, shine light thru mask and the tube and a detector measures the correlation
12	benchmark bands that are fo/no-go that you use to compare and bound the band location
13	detectable 1% grid that you use behind the tube that you measure off and the bands interfere with the grid in some way that is detectable
14	use grid with a differential sensor that looks at adjacent squares, squares form frames for the sensors
15	magnify cells and use pattern recognition to size and count cells
16	add a chemical that selectively flouresces cells
17	put in micro sphers that selectively connect to cells, they are magnetized, detect magnetic field. move them around
18	wool in tube, cells stick at different locations
19	run two fiber optics up like electrodes, emitter and detector pair or you have two detectors as a differential pair and light could come from outside
20	two electrodes of different type material, measure the galvanic action or temperature assuming it changes from layer to layer
21	put mini transformer around tube, the layers form different cores that change inductance and resistance of the transformer. Or, one tube long transformer with many many taps so no moving parts. Make use of differential like in an LVDT
22	tag cells with radioactive element and detect radiation
23	expose tube to radiation then scan tube and measure radiation intensity
24	tag with radioactive element and detect radiation
25	run the coil up the side and point at it instead of around it
26	one tube inside that you blow air down and measure intensity
27	a single/multiple linear ccd sensors that have 300 dots/inch and scan whole tube at once without moving with lenses
28	sliding lens to save space
29	use prism to have different colors show up in different places, maybe two so that the detector(s) does not move
30	two prisms/lenses that create interference based on wavelength
31	transmission of ultrasound through the tube

32	radioactive tag and an x-ray
33	use v-mirrors to make laser go through more times to increase intensity drop
34	expose entire tube to heat then scan with temp sensor to get layers
35	use metal strip in side of tube to conduct heat to sensor
36	stick thermocouple down in side
37	reference color from monochrometer, sensor compares reference color to the color it sees
38	use two filters and analog sum them to get one signal instead of two
39	two wires pass up tube and measure resistance change
40	light source, lens, and ccd detector
41	ultrasound down along axis of tube, measure reflections of layers
42	magnetic beads or rings of different densities
43	vision system mimics a human user
44	colormetric absorption, white light, diffraction grating, and sensor
45	laser shines down tube, end detector measures ID, mirror and photodiode measure bands based on intensity
46	add reagent that causes exo/endothermic reaction, measure the resulting temp
47	paint shop color meter
48	no float and float,--get two pieces of data
49	morie effect using lines htat interfere with the band lines
50	make a magnetic shadow instead of optical
51	use a light rod that doubles as a float or a dot that moves up and measure intensity, sensor could be inside
52	capacitance probe, rod on the inside, and a ring moves up on the outside
53	HWH scanning laser dot
54	stick pH probe through the tube
55	meter out small drops from the tube, when their weight changes its a new layer
56	measure force/pressure to push layers out through a little hole
57	differential sensors that scan up the tube, use frequency measurement on the other side, or amplitude
58	laser deflected based on refraction, use quadrant cell on the other side
59	Autoreader filter concept using color filters
60	use row of fiber optic sensors up the side of the tube, maybe just a bunch around the float
61	use laser and measure intensity
62	for interference use a slit at an angle athat moves up and down

Patient identification

1	a handle on the tube has a bar code on it. The handle either runs the full length or else it is a square tab connected to one end
2	hold tubes in place by taping down with a barcode sticker
3	a cap goes over one end of the tube with a bar code on it
4	ink jet printer bars on the tube above the fill ine
5	fold form ID bar code over the tube that matches another on the form
6	put a barcode sticker on the tube that is clear
7	magnetic strip on the tube either on one side or around
8	glue on a computer chip that you can read and write to
9	grind notches into the tube and use a bump reader to detect them
10	use notches like the fish ID Ben saw on a Discovery show
11	laser etch an ID into the glass
12	finger print ID of patient as a code
13	fluorescent tag on tube to ID it
14	ink that burns under laser then burn bar code into the ink
15	color code tubes to forms and have a color dot reader
16	code positions in the centrifuge, use 1-20 on it and on the forms
17	ID making machine that you stick the tube and form into beforehand
18	put the form and the tube into the machine as a set
19	tube and form come pre-IDed as a set
20	social security number as an ID on the tube that get written on
21	put name and number on a small form on tube and then print resutls on that form so that the user does manual transfer from there
22	simultaneous ejection of the tube and the print out where the name is written on the tube before it goes in
23	machine connects tube to form. use two holes and thread the tube, tape, or use an adhesive
24	braille bumps in the end cap press against a sensor. maybe use centrifuge force
25	worm optical hunk on the tube or on the end cap
26	radio transmitter like BD people use to go through doors
27	shipping tags and manual writing
28	rubber stamp that prints ID on the tube
29	charge a capacitor to a certain voltage
30	computer and punch reader
31	barcode scanner in the machine. Insert tube after scan and hit button. The machine matches ID to position
32	put ID's on a rack that goes into the computer
33	start with two ID's on tube, take one off and put it on a patient's form
34	with the octopus idea put ID bar on cap and tube combination, write name on the cap and track the sample with the cap
35	bar code tab on tube
36	stopper color matches with number
37	float color matches with number

38	ID tube at the location you take the blood, have a machine IDer put names on it
39	Fedex paperless transactions
40	have the machine be an ID generator
41	calculate blood type and use it to check against patient
42	stick tube in hole only one at a time forced to ID tube before machine advances, ID based on position. if the machine is remote write name on a tag or holder to be read
43	patient gives the blood drawer and ID that gets stuck on tube
44	OCR finger print scan

Blood transfer to machine

1	put arm into slot or finger into a hole/on pad and the machine auto takes the sample
2	a tube runs from a needle to the machine only the tube and needle are replaced
3	use a tube with a needle on one end and a pipette on the other hand
4	have only a hole that the tubes are dropped into and a light that indicates that the tube was received
5	put cartridge in conjunction with auto blood sucking
6	rubber holder that wraps into centrifuge
7	place tubes into tray of centrifuge manually
8	put cap on container that has a hole that seats the end of the capillary tube. Pipette blood up a tube inside into capillary. When you press doen a hole opens up that lets air into the container
9	auto feed and sort the tubes; the user just dumps them in
10	the rack that the tubes come in goes into the machine and it is also disposable
11	have the machine accept more than one rack
12	drop tubes into a can and the machine takes them out and puts them back in. It could be a sharps container. tubes are spun in the can or the rotor is auto-loaded
13	combine can with auto finger prick, the tubes come in the can empty
14	disposable needle and rubber tube hooked to each EZ-Prep
15	auto load/eject cartridge like a VCR or CD player
16	machine feeds a tray in one side and out the other as they finish
17	tube handler, a clear tube that is thick that fits over the thin tube
18	a handle/container that the machine removes the actual tube
19	indexing carousel that comes out which is disposable and indexed
20	machine sloshes tubes for you if you put them in immediately
21	hand held shaker

Overall system configuration / industrial design

1	hand held device which is placed against the limb of a patient
2	disposable package at the end of anlaysis
3	flexible magazine of tubes
4	tubeless integration of blood extraction and analysis
5	sequential linear conveyor belt
6	mounts underneath a cabinet like a microwave
7	tower that can sit up against a wall
8	remote machine, the guts are somewhere else, like a mail slot
9	just dump tubes in and they auto align
10	prompt driven labeling
11	computer linked to doctor's database
12	magazine of unfilled tubes
13	note book configuration
14	call up on screen what tube is in process, how far to go, etc.
15	continuous processing
16	inventory bays
17	priority interrupt tube processing
18	express line, multiple sensor stages, "ten items or less" supermarket check out idea
19	whimsical cool shapes: BD MIT, red blood cell
20	transparent machine body

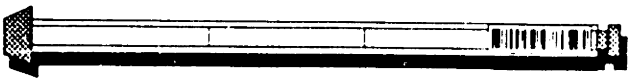
Appendix E: Three System Concepts

Standard Card Form and Tube Unit

FORM QBCCAPILLARY

0123 456 789

BECTON DICKINSON

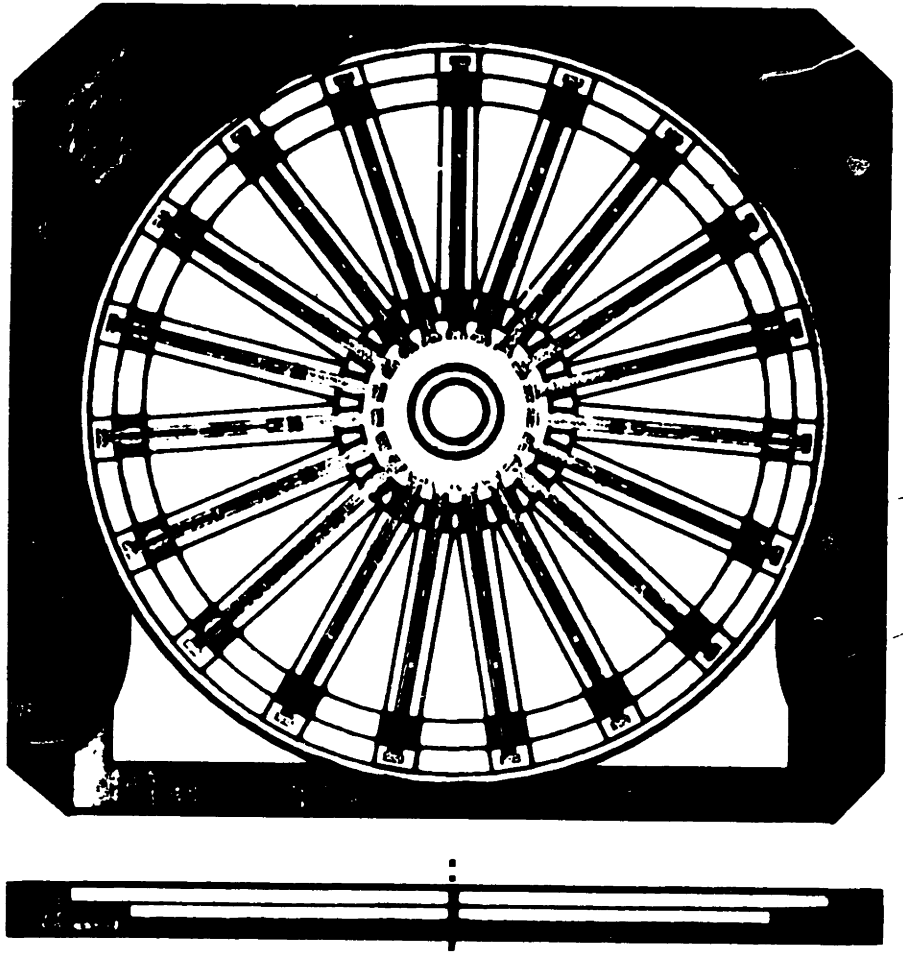


Remove Tube Only After Completing This Form

Date:	
Time:	
Patient Name:	
Social Security Number:	
Address:	
Doctor's Name:	

Attach Printed Hematology Results Here.

CAROUSEL & CASE UNIT

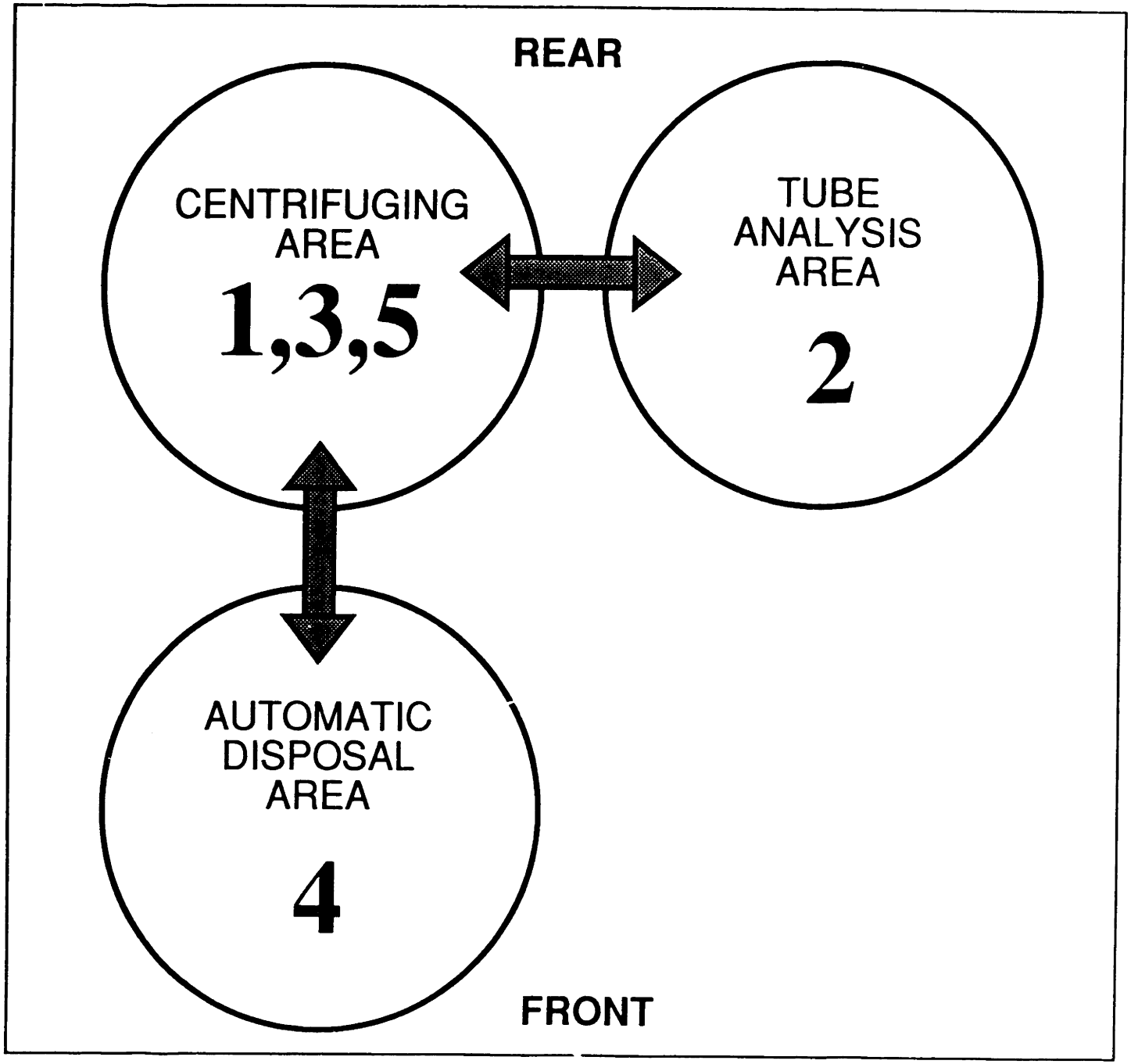


Carousel

Case

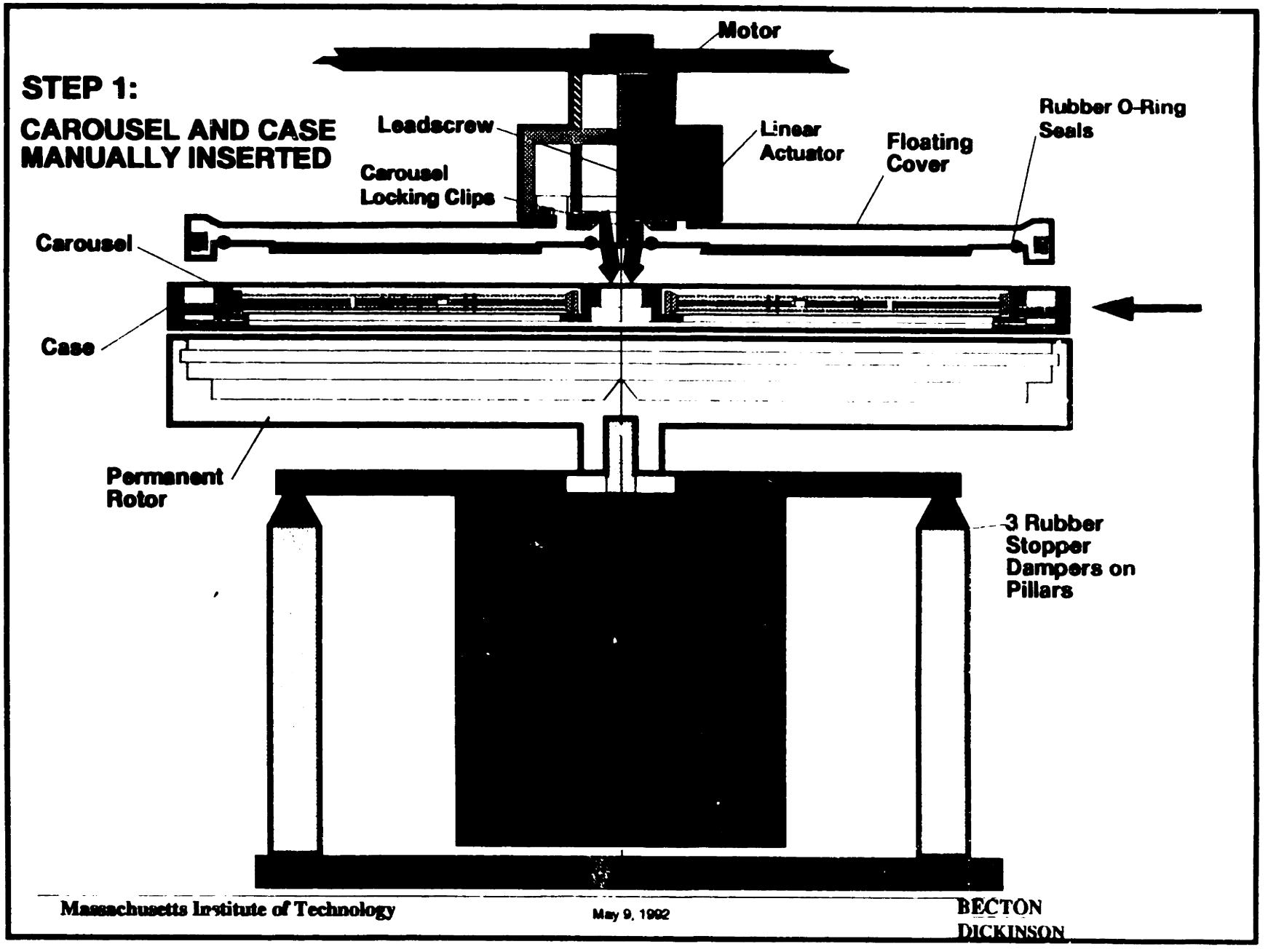
Spring Loaded Carousel Locking Mechanism

TOP VIEW OF "FIBER SCAN"



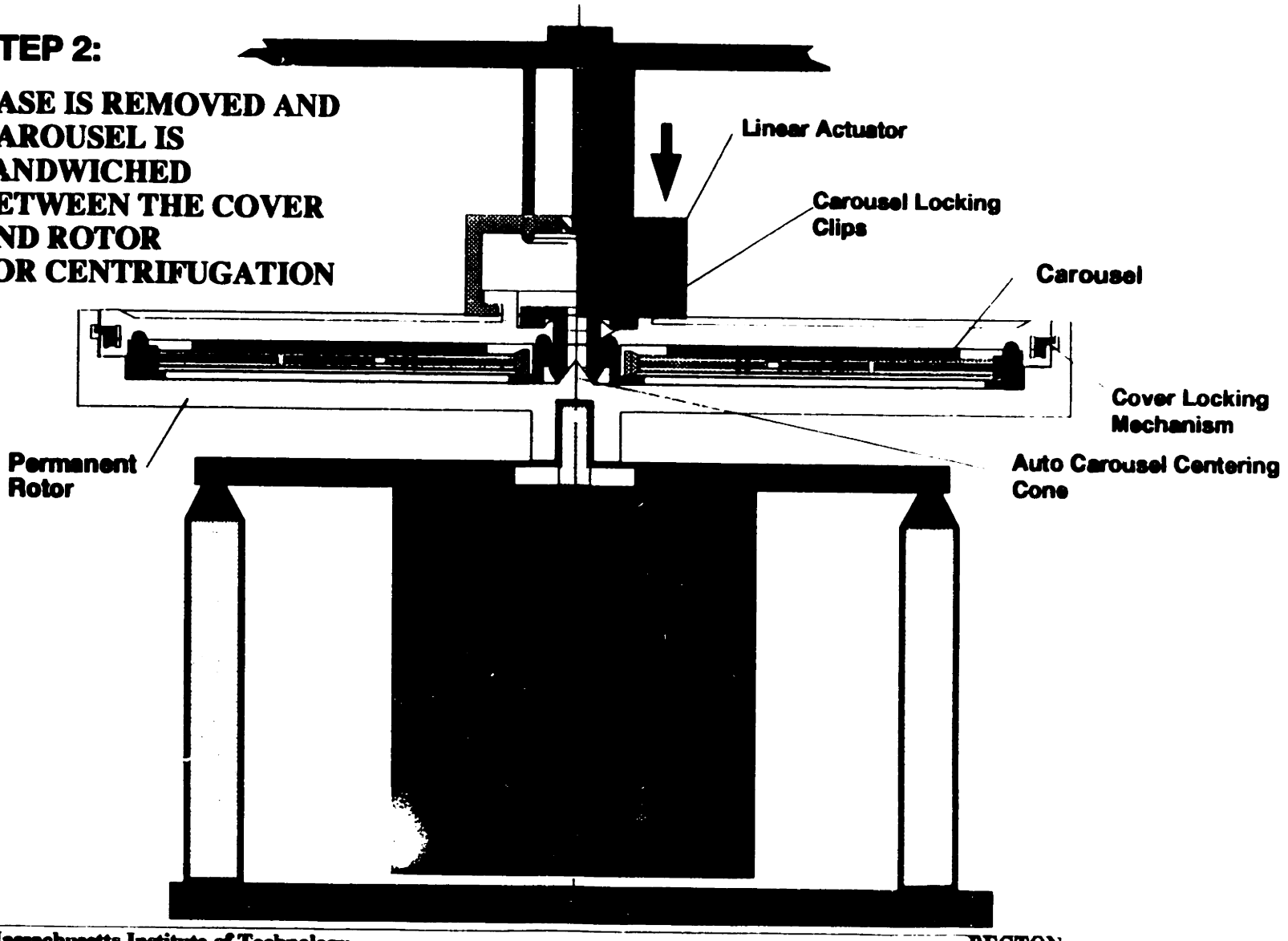
SEQUENCE OF TRAY MOTIONS :

1. Tray is inserted and centrifuged
2. All tubes are analyzed
3. Tray is returned for disposing tubes
4. Tubes are disposed
5. Empty tray ready for removal


STEP 1:
CAROUSEL AND CASE MANUALLY INSERTED
Motor
Leadscrew
Linear Actuator
Floating Cover
Rubber O-Ring Seals
Carousel Locking Clips
Carousel
Case
Permanent Rotor
3 Rubber Stopper Dampers on Pillars
Massachusetts Institute of Technology
May 9, 1992
BECTON DICKINSON

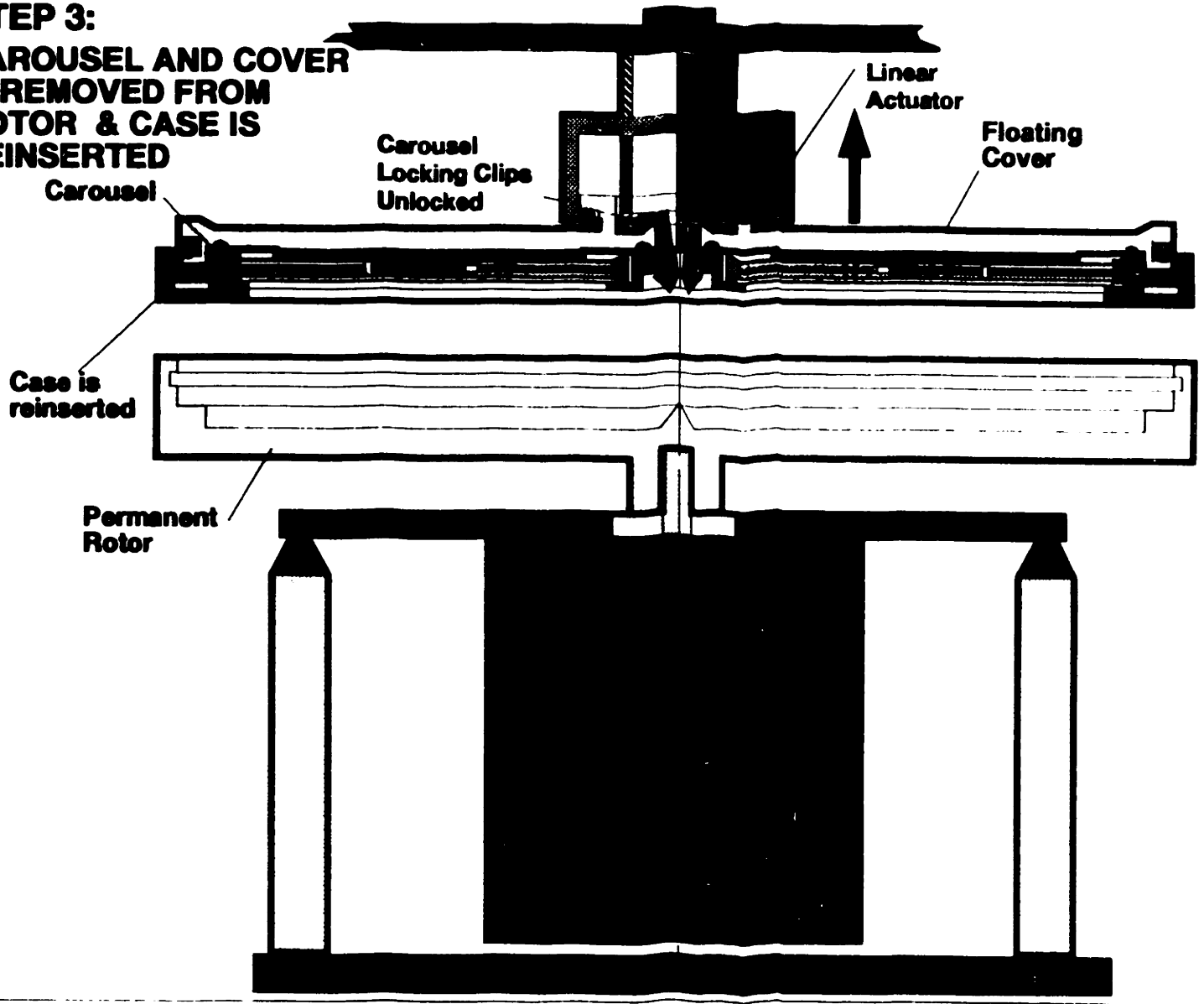
STEP 2:

CASE IS REMOVED AND CAROUSEL IS SANDWICHED BETWEEN THE COVER AND ROTOR FOR CENTRIFUGATION



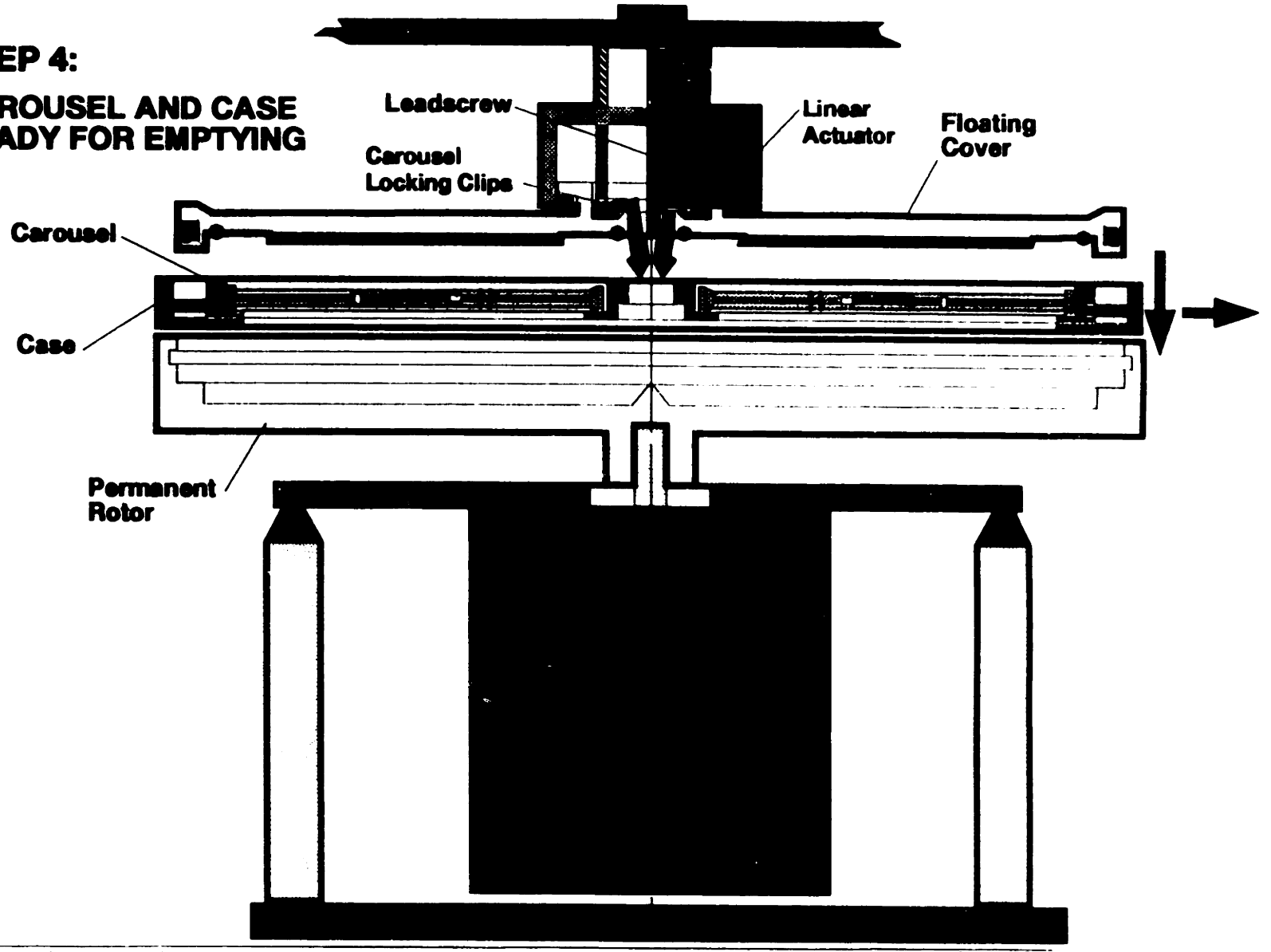
STEP 3:

CAROUSEL AND COVER IS REMOVED FROM ROTOR & CASE IS REINSERTED

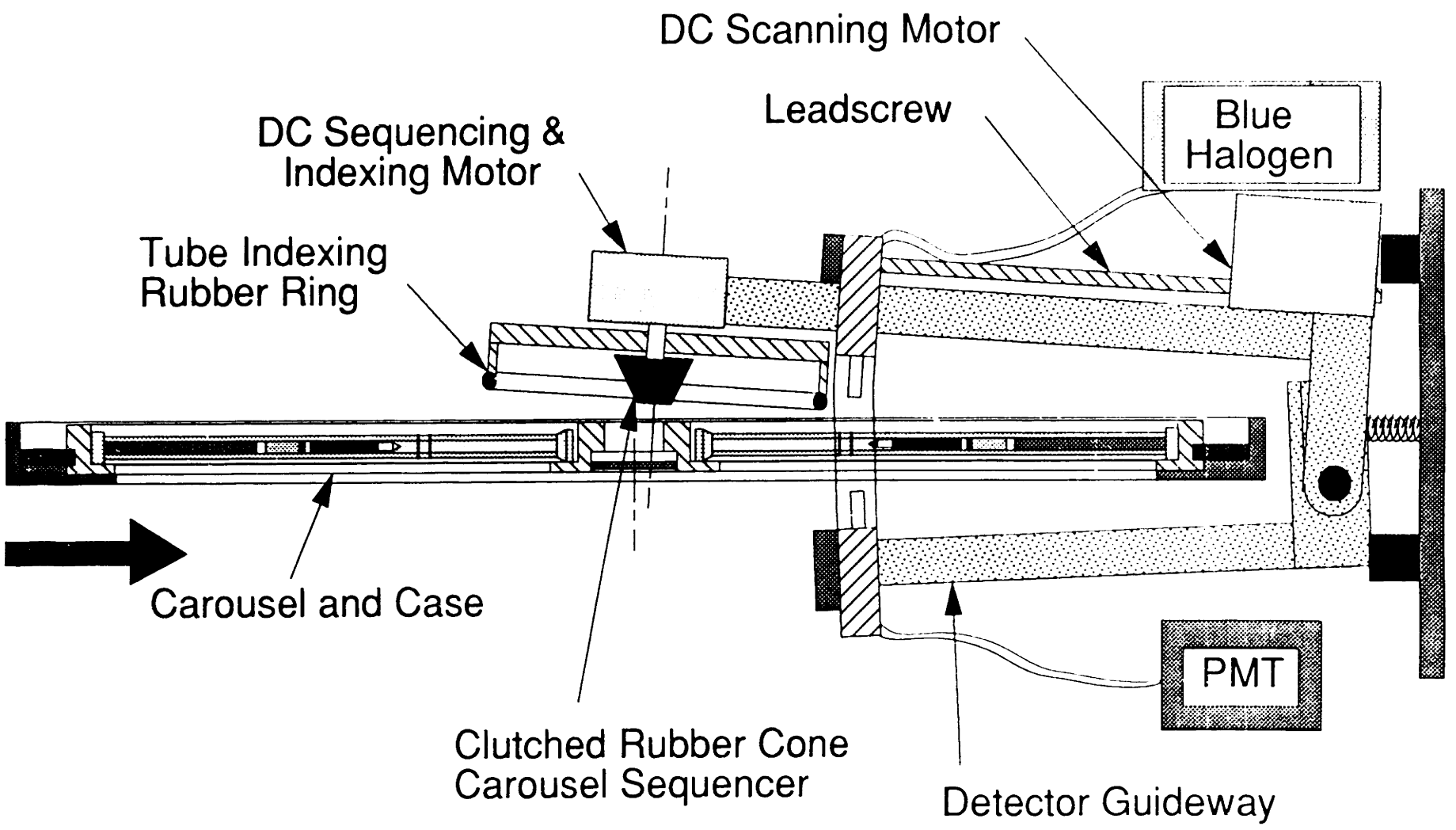


STEP 4:

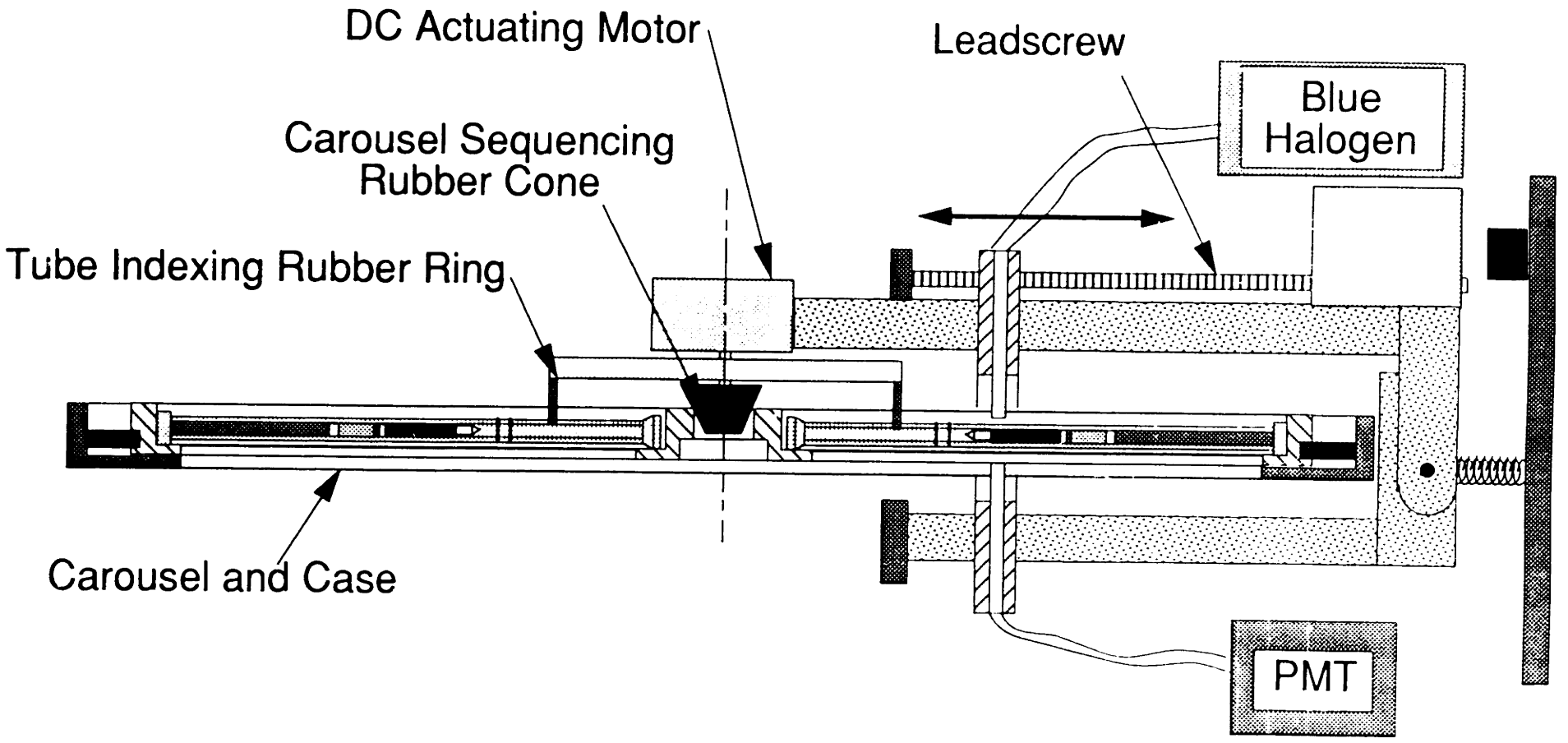
CAROUSEL AND CASE READY FOR EMPTYING



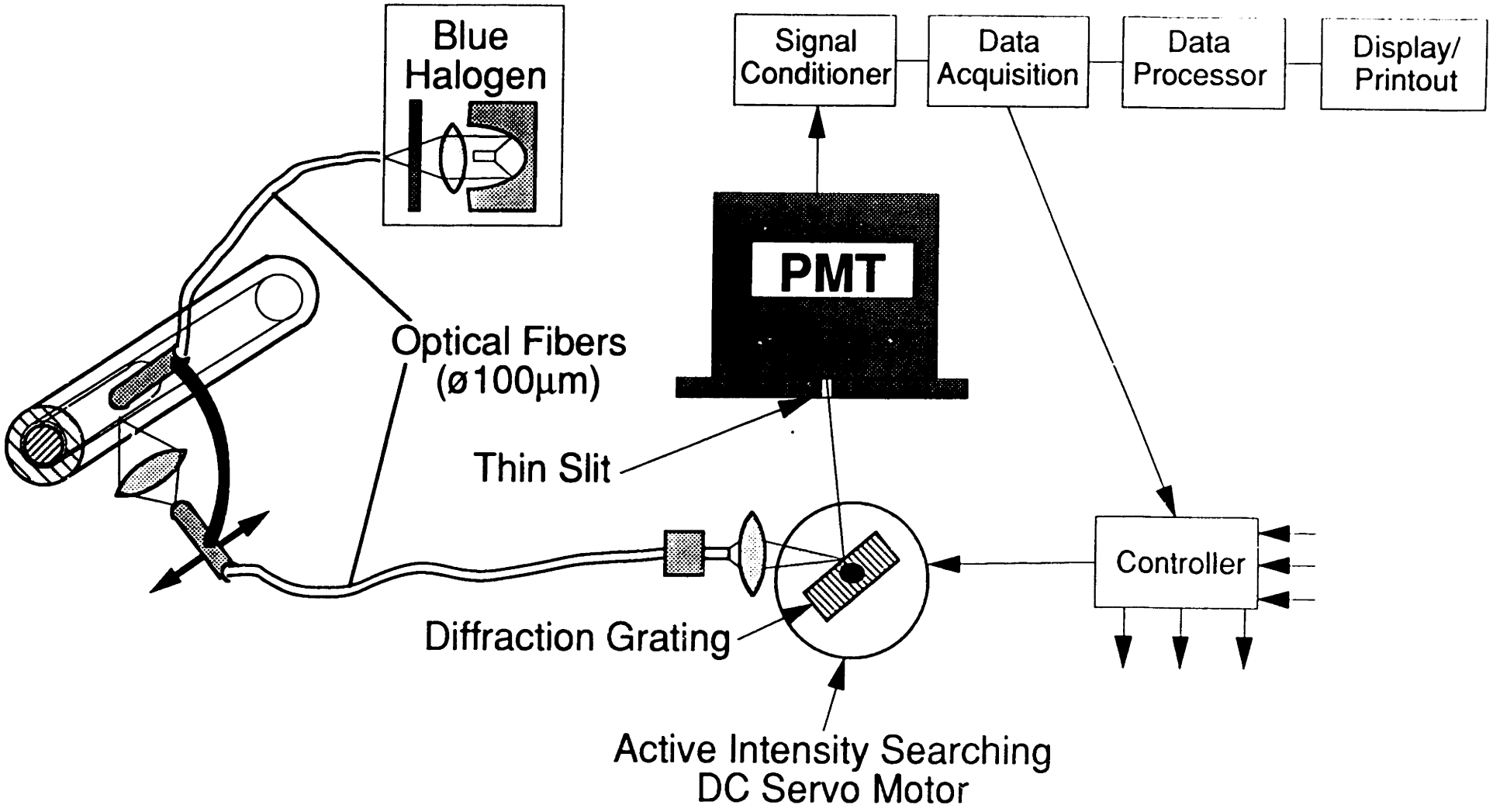
CENTRIFUGED TUBES SHUTTLED TO "JAWED" TESTING AREA FOR ANALYSES



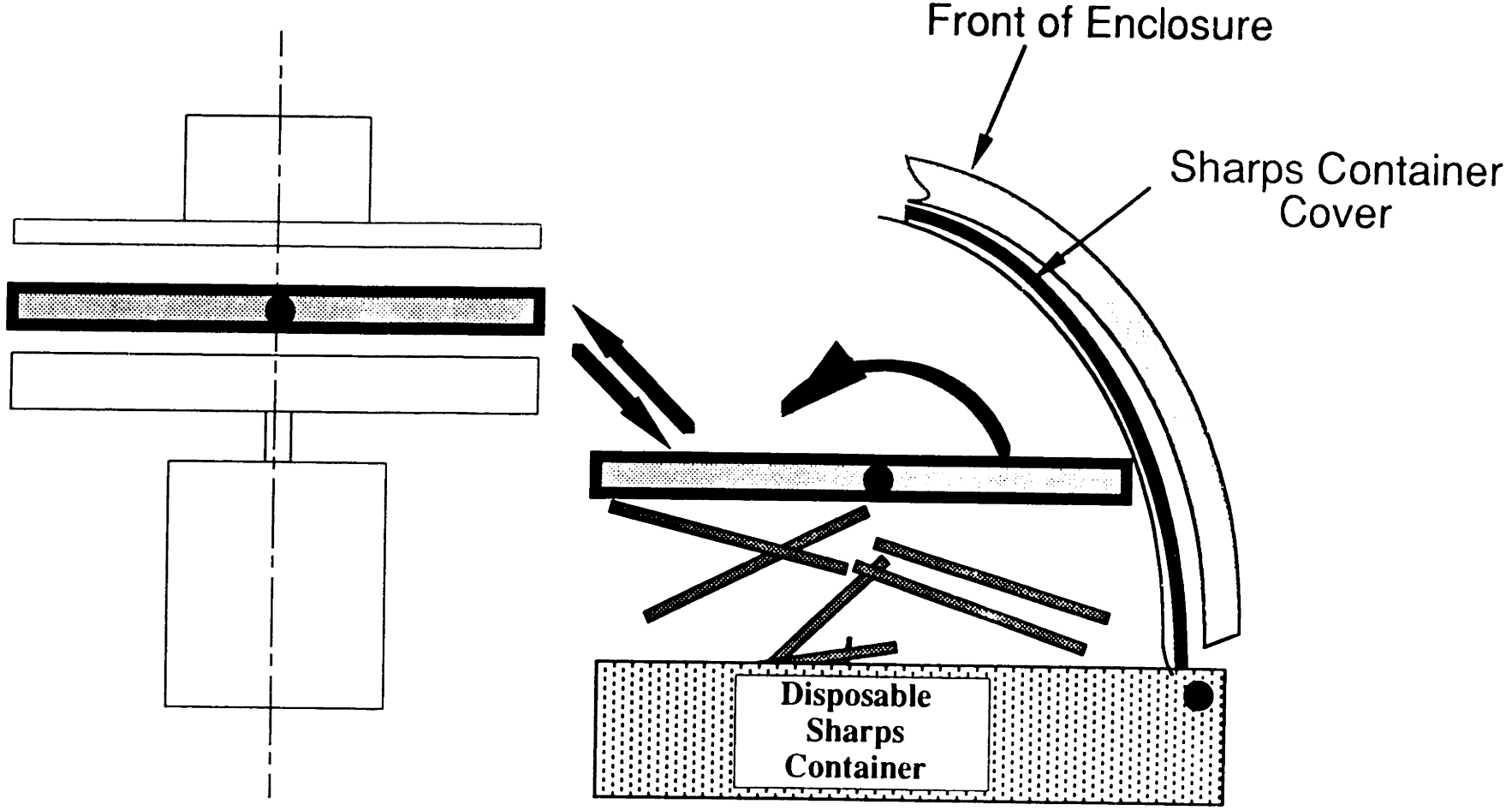
TUBE SCANNING, INDEXING, and CAROUSEL SEQUENCING



FIBER SCAN Method



AUTOMATIC TUBE DISPOSAL



FIBER SCAN

Customer Needs Met

- Achieves Level of Accuracy of Coulter STKR
- Insert Case with Carousel, Walkaway, and Return to get Printed Results
- 20 Tube Batching Capability
- Analysis Time per CBC with Batch Size of 20: **36 seconds**
- Automatic Tube Identification
- Features for Minimizing Contact with Blood
  - Option for separate automatic blood transfer unit (from Vacu-tainer to capillary tubes to eliminate blood exposure and aerosol problems)
  - Automatic tube disposal
- QC Information Saved on Internal Memory Chips and Analyzed to Recognize Drift
- Words Used for Identifying Any Errors
- Interfaceable to Laboratory Information System or external personal computer via RS-232 port

FIBER SCAN

Performance and Cost Specifications

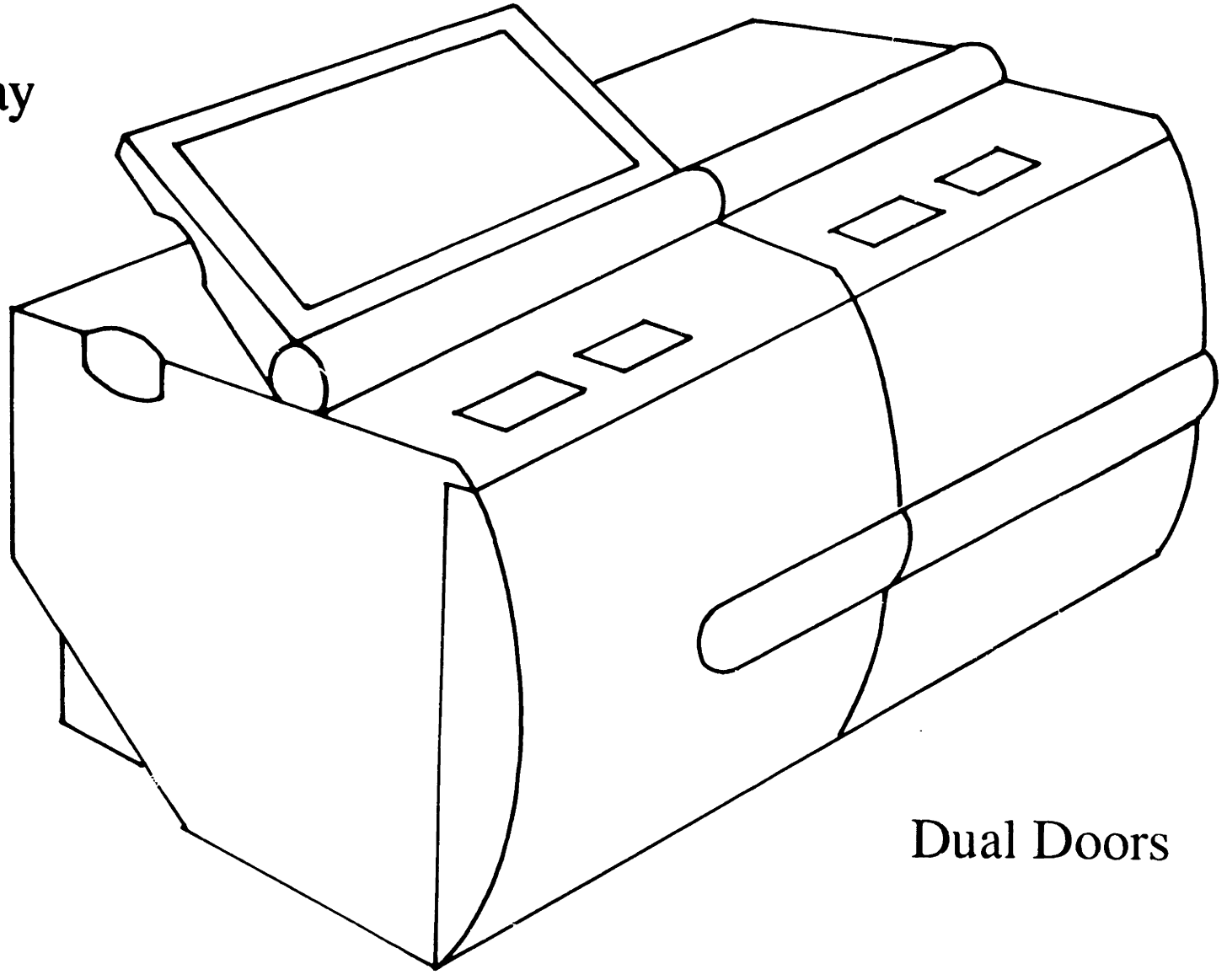
- Able to Detect and Measure Fluorescence
- Precision: 0.0002 inch
- Accuracy: 0.0005 inch
- Tolerance Issue: Pre-measured and Pre-Bar Coded at Factory
- Speed:

Centrifuge Time:	300 seconds
Scanning Time per Tube:	15 seconds
Analysis Time per Tube:	5 seconds
Material Handling Time:	10 seconds
Total Analysis Time for only 1 CBC:	5.5 minutes
Total AnalysesTime for 20 CBC's:	12 minutes
Printout Time per Tube:	5 seconds

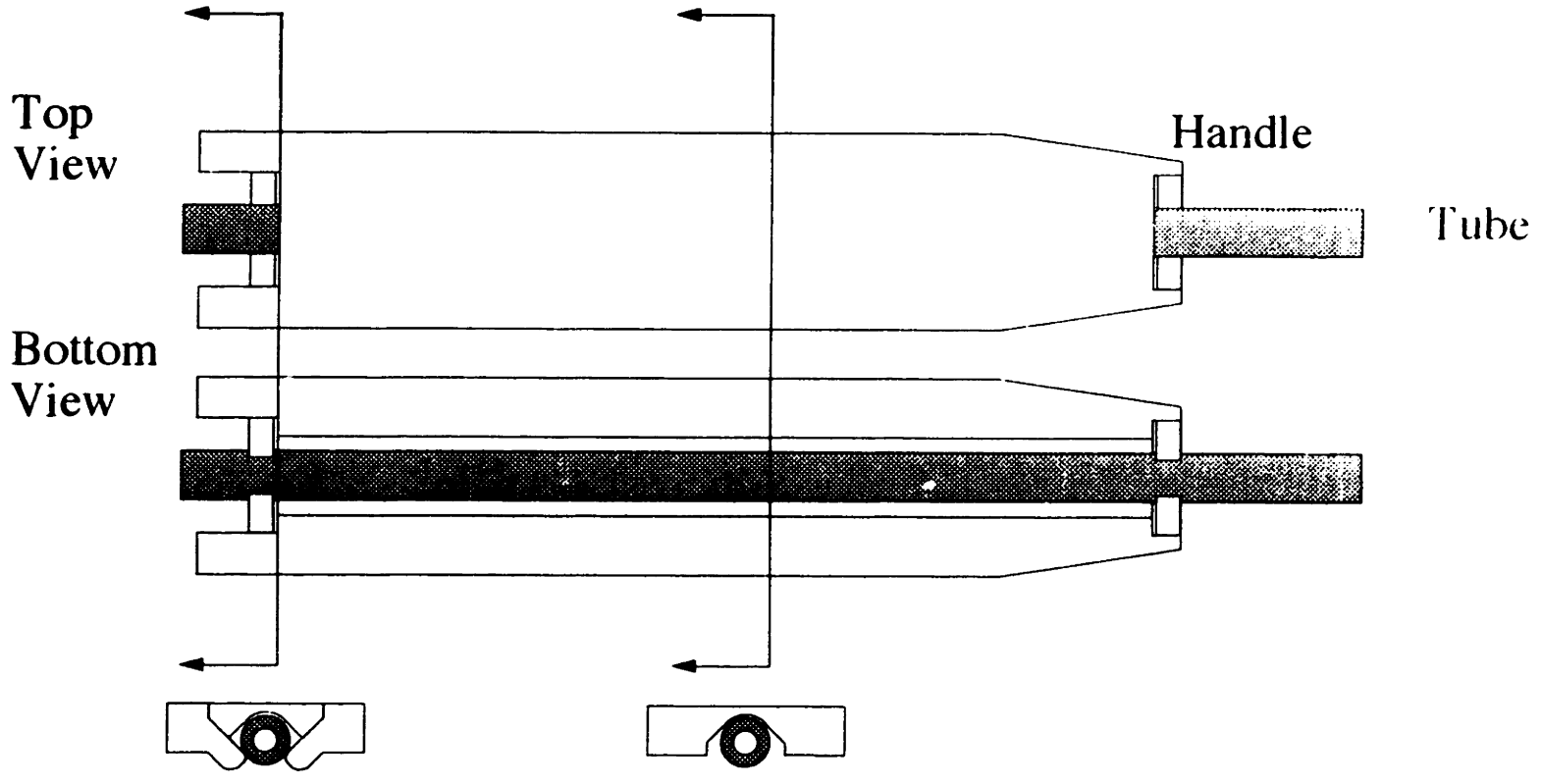
- Estimated Material Cost per Unit: $2,500
- Estimated cost per unit including labor, material, and overhead: $4,000

"DOUBLE ROTOR"

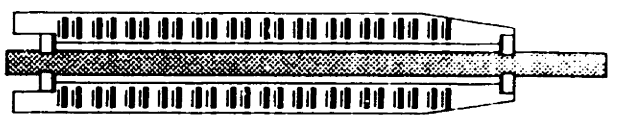
"Dual Rotor"



Tube Handle



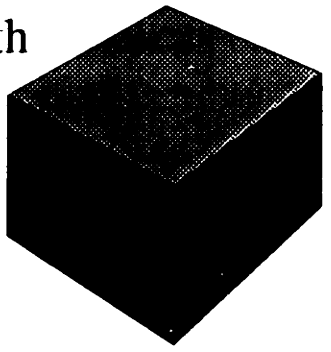
Benjamin Matthew Linder
373-94-8284 5/5/92 5:45
Run CBC on QBC Walkaway



Patient Identification Using an Auto-Labeler

Auto-Labeler

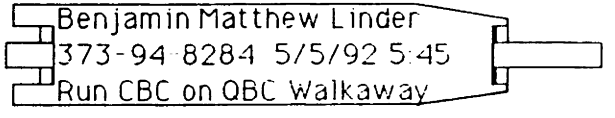
1. User places empty tube with handle into auto-labeler



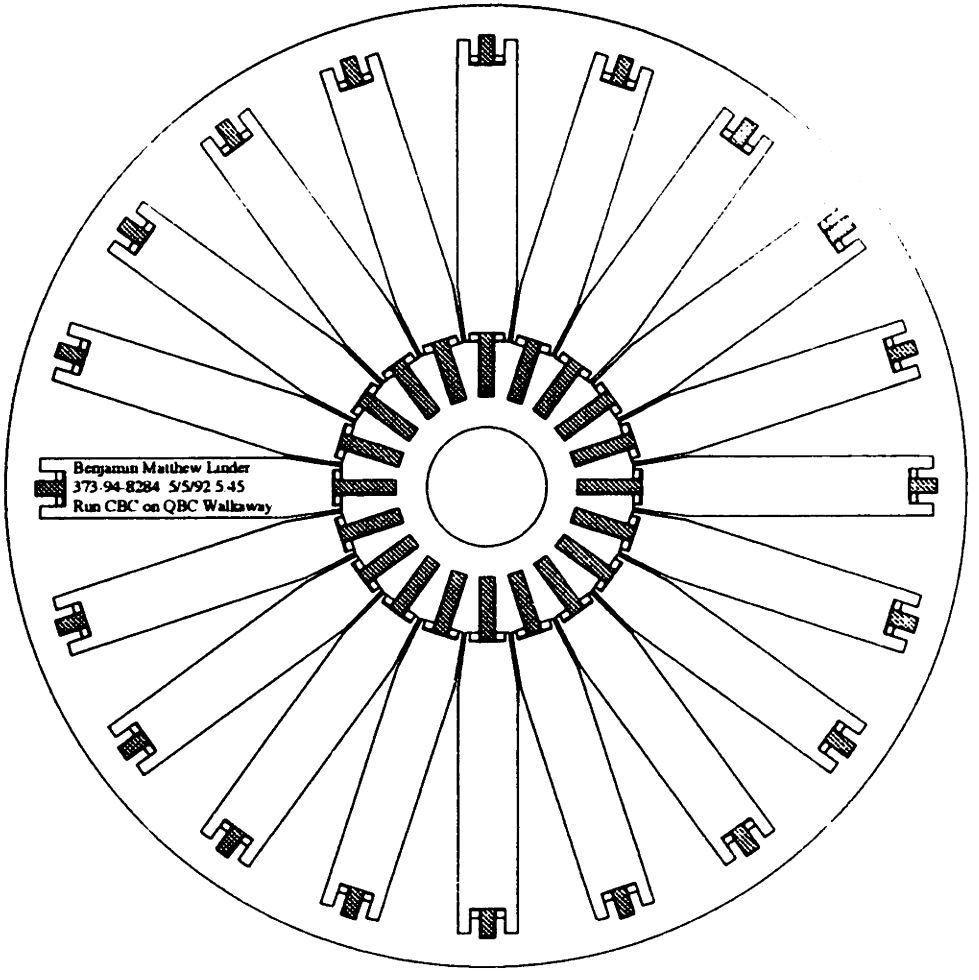
2. User types in patient name, date etc

3. Outputs tube and handle with a unique barcode storing patient information

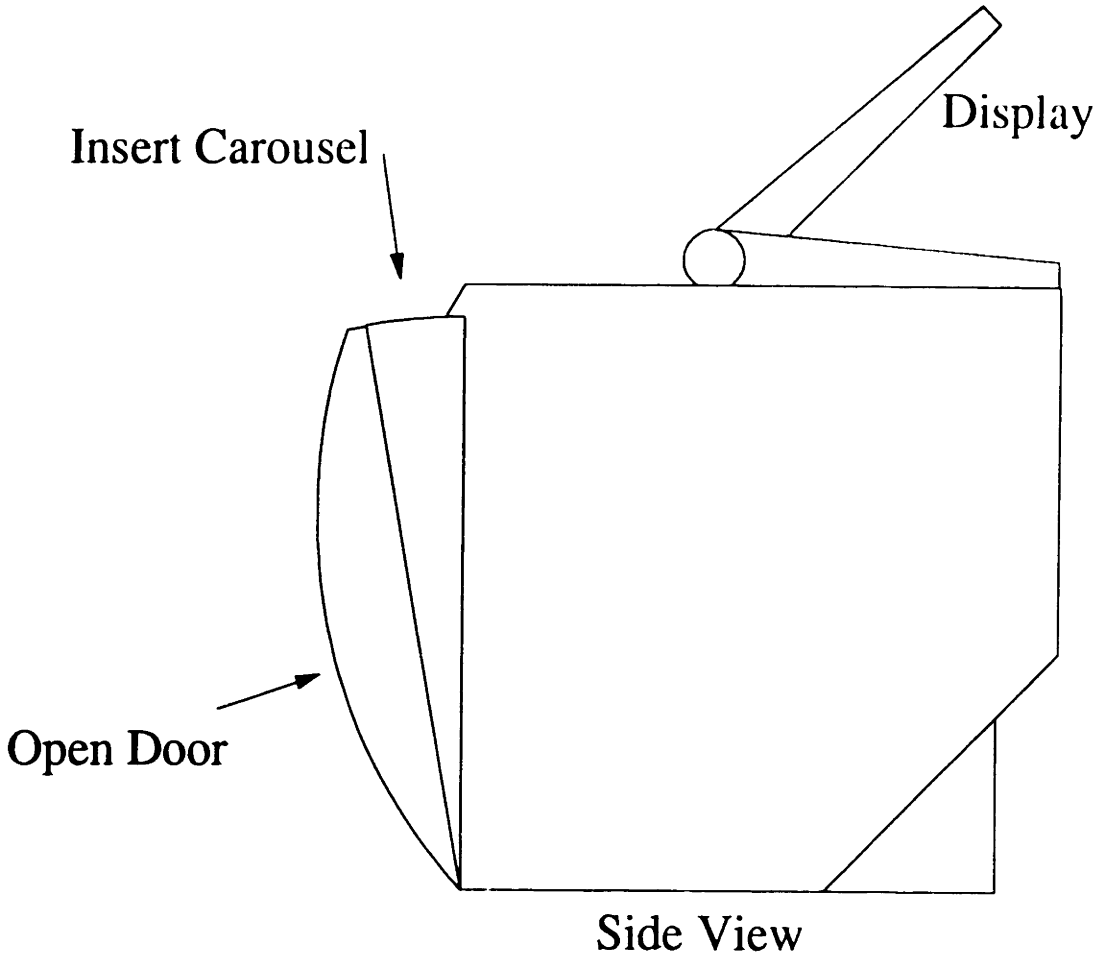
4. User also writes on the handle patient information and test type



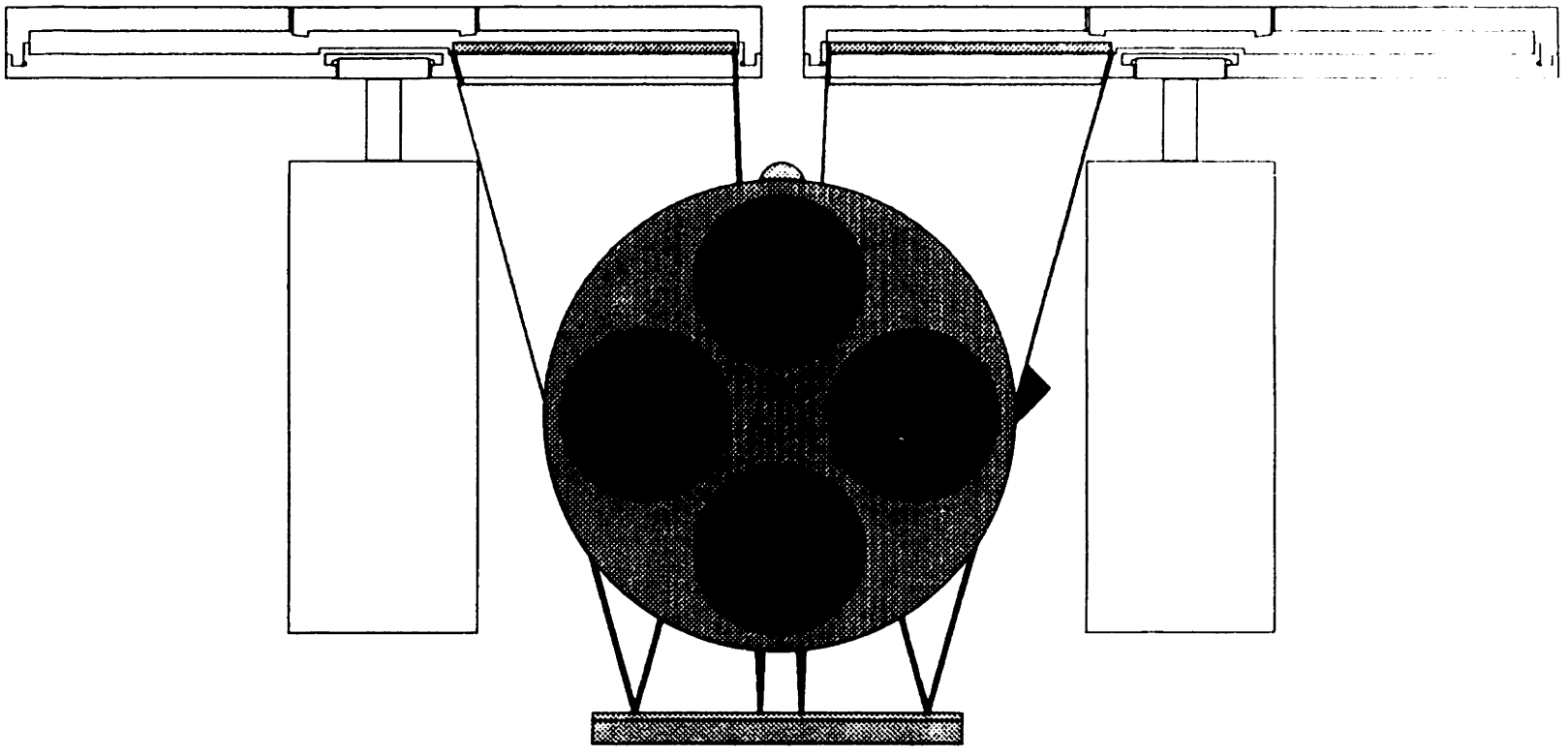
Top View of The Carousel With Tubes Loaded



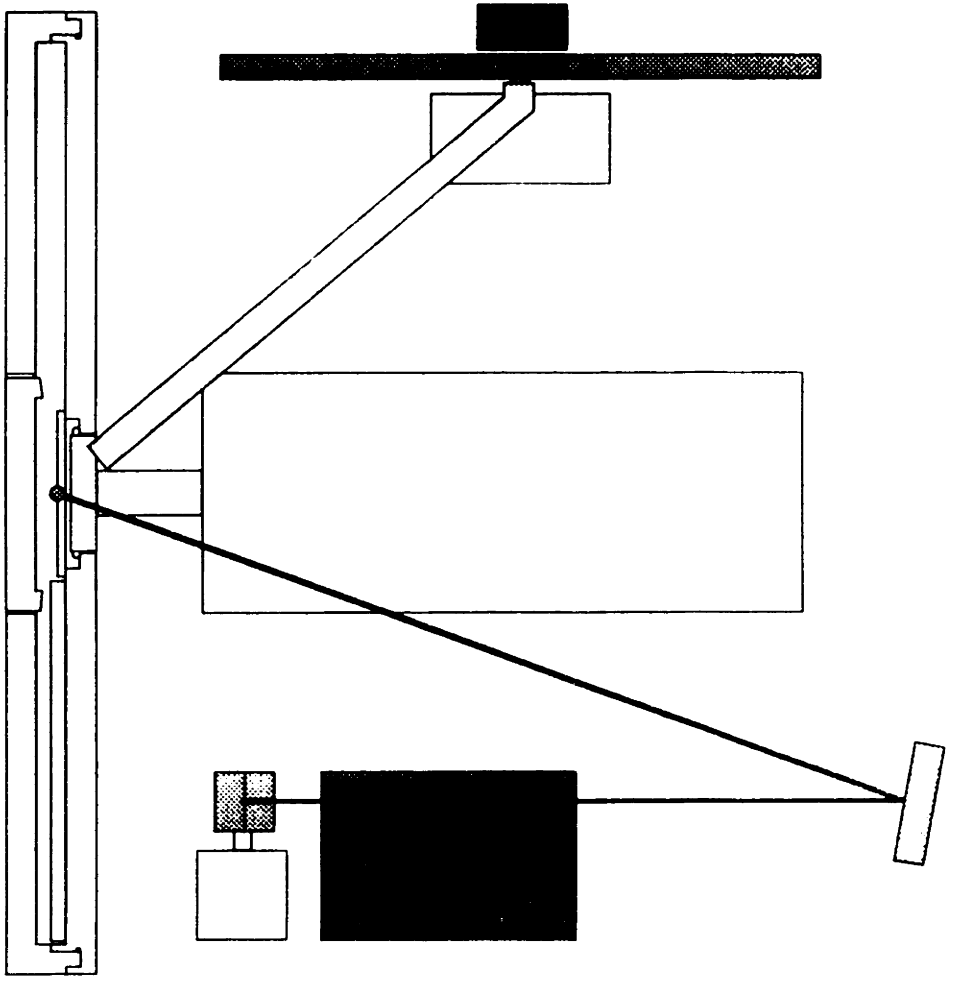
Loading the Carousel



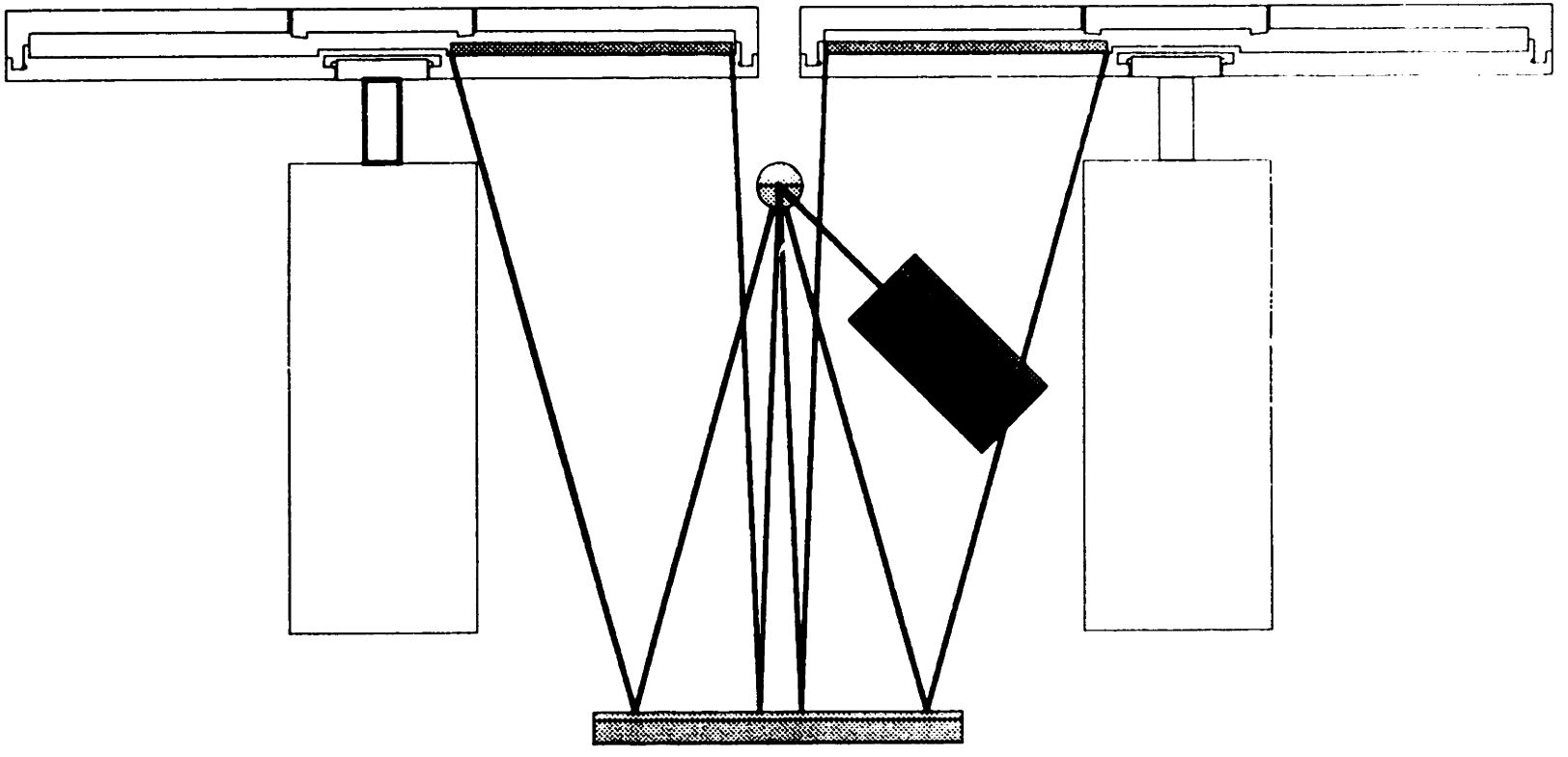
Top View of the Source and Detector with the Centrifuge Motor and Carousel



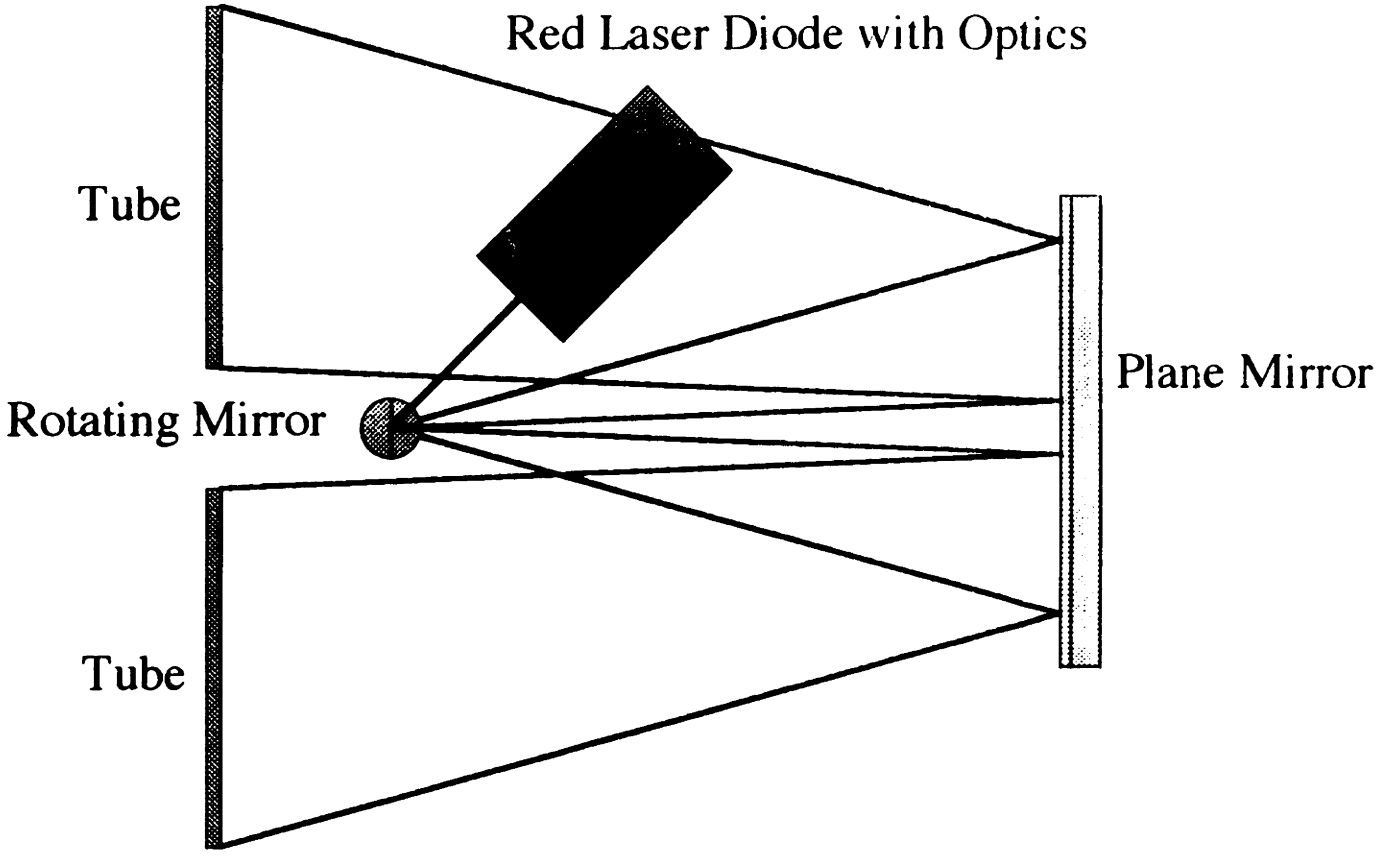
Side View of the Source and Detector with the Centrifuge Motor and Carousel



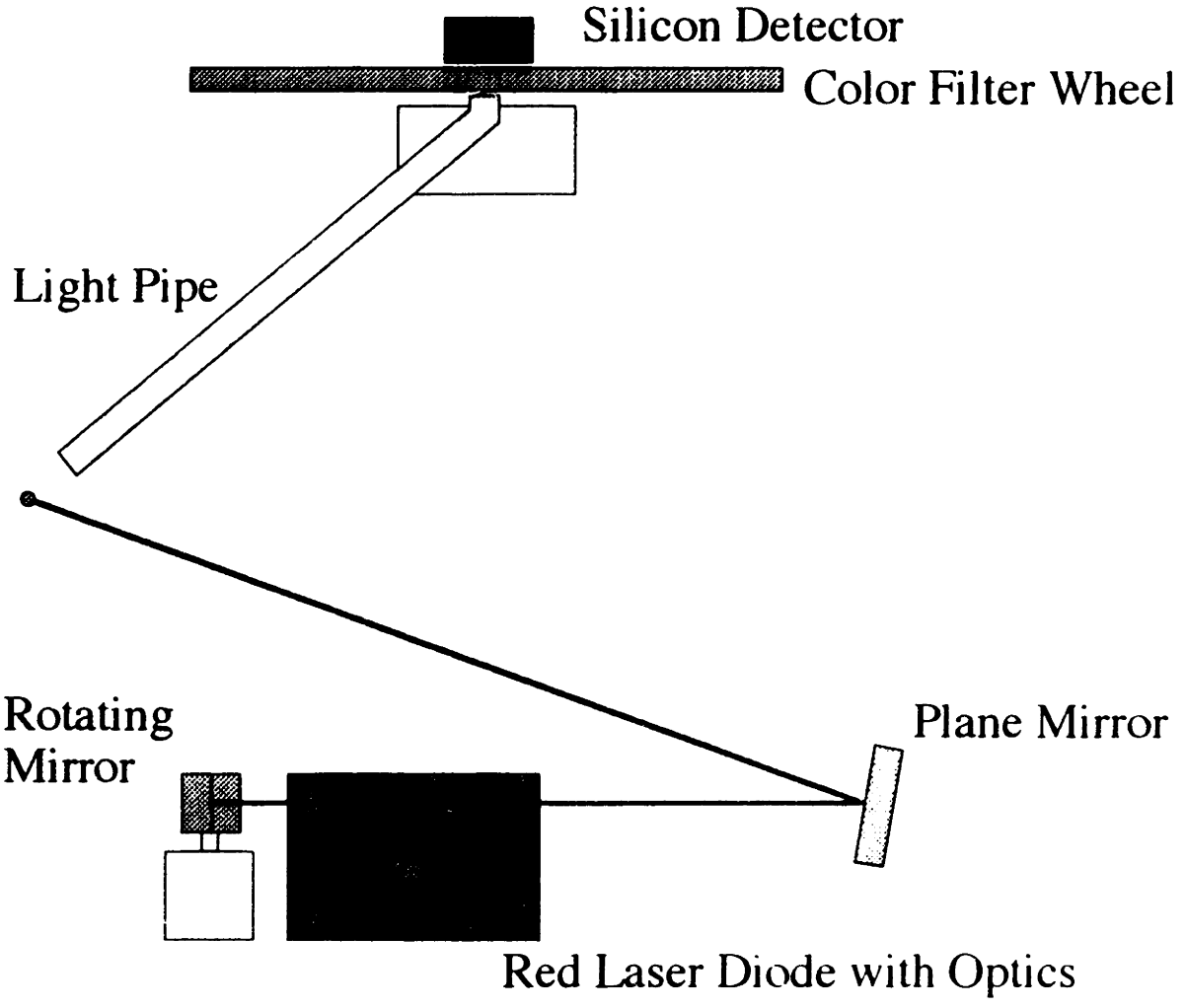
Top View of the Source with the Centrifuge Motor and Carousel



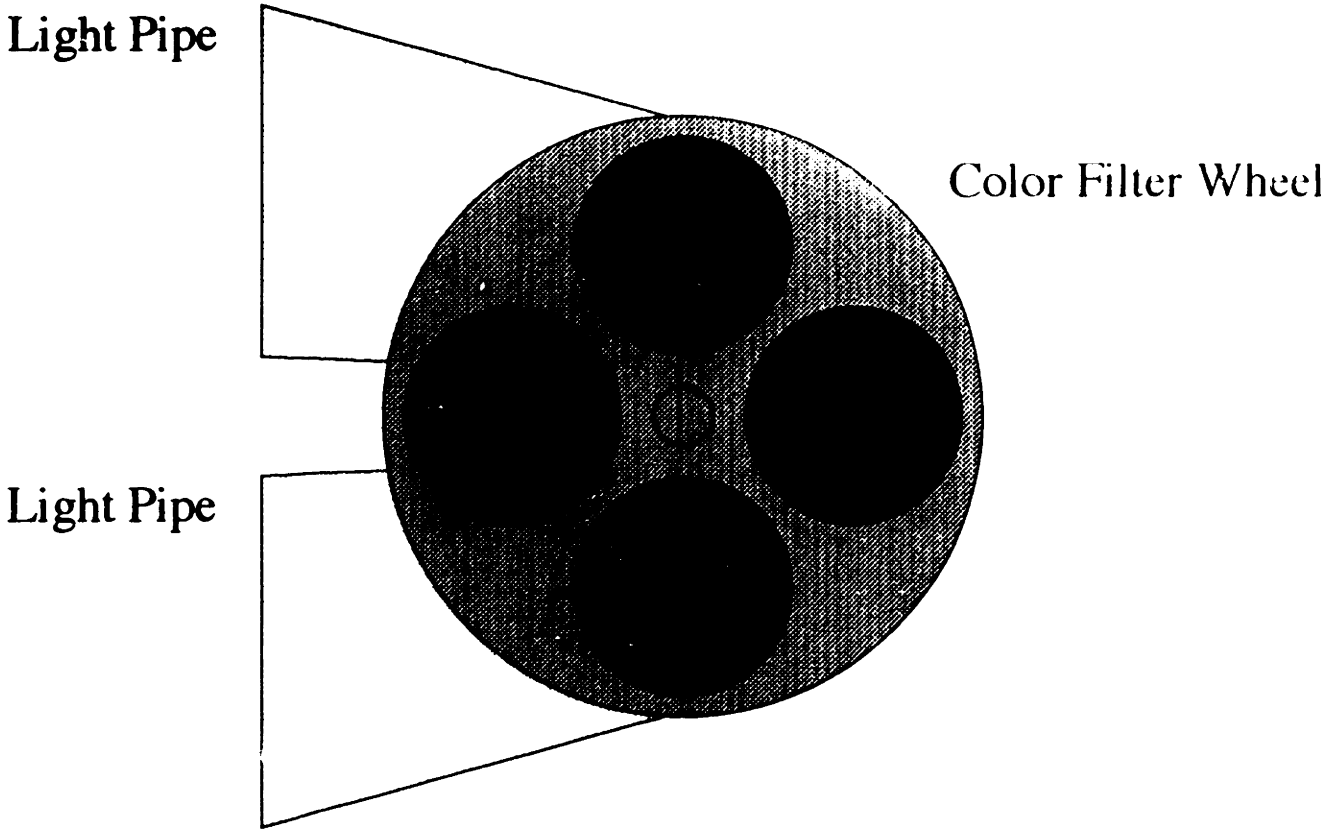
Top View of the Scanning Laser Light Source



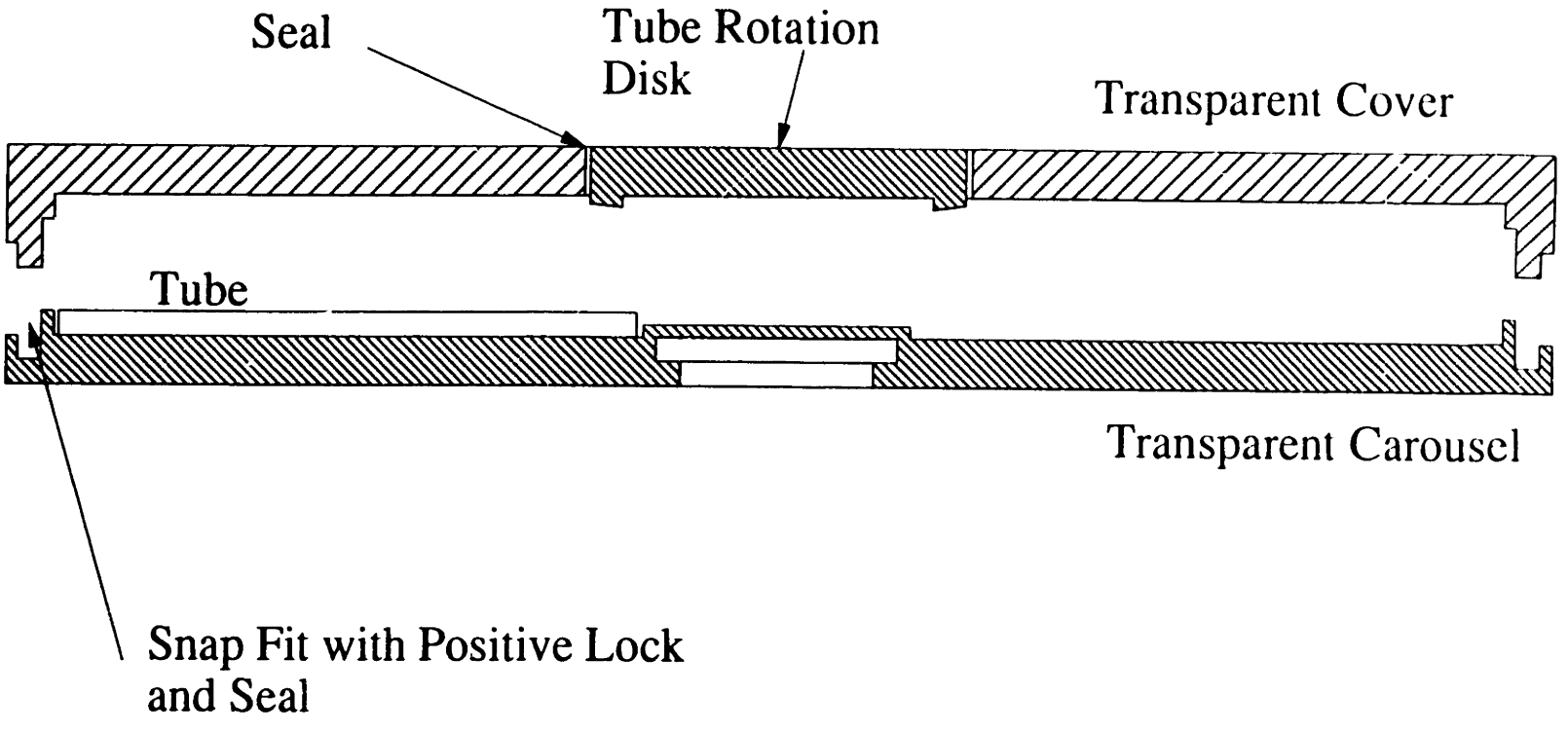
Side View of the Source and Detector



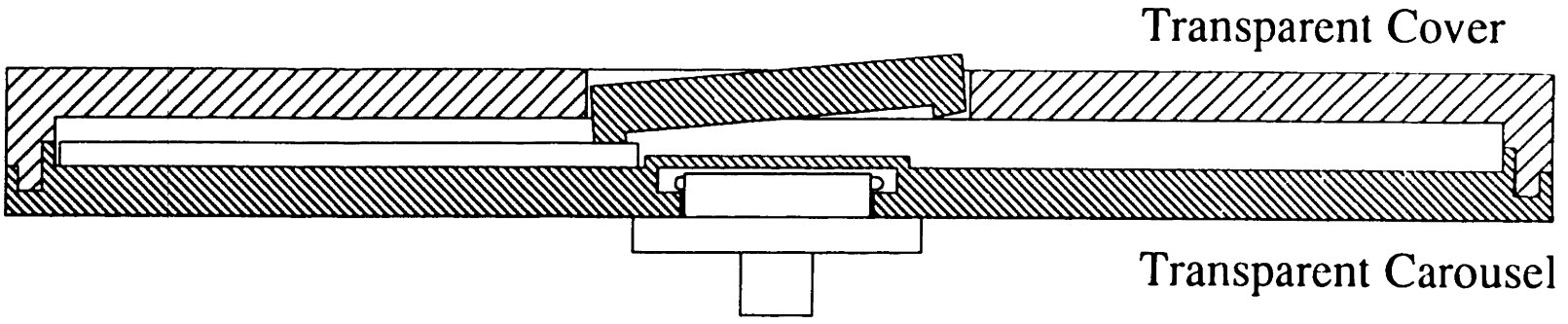
Top View of the Color Filter Wheel and Light Pipe



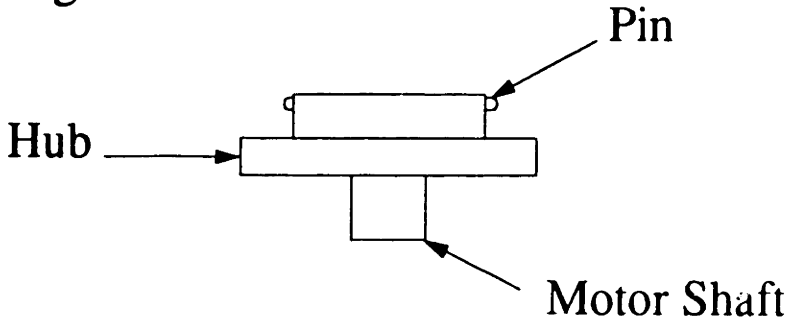
Section View of the Carousel



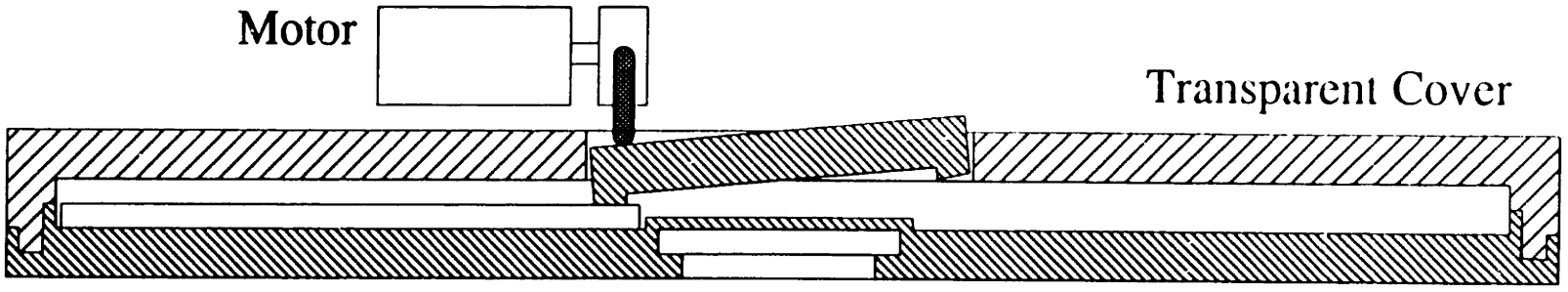
Carousel Mounting



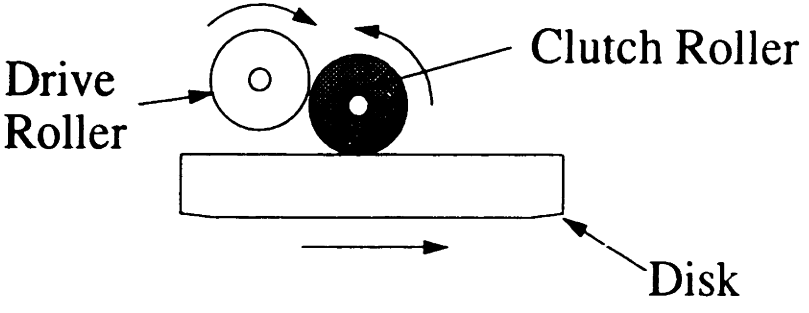
Mounting Hub
with Spring Pins



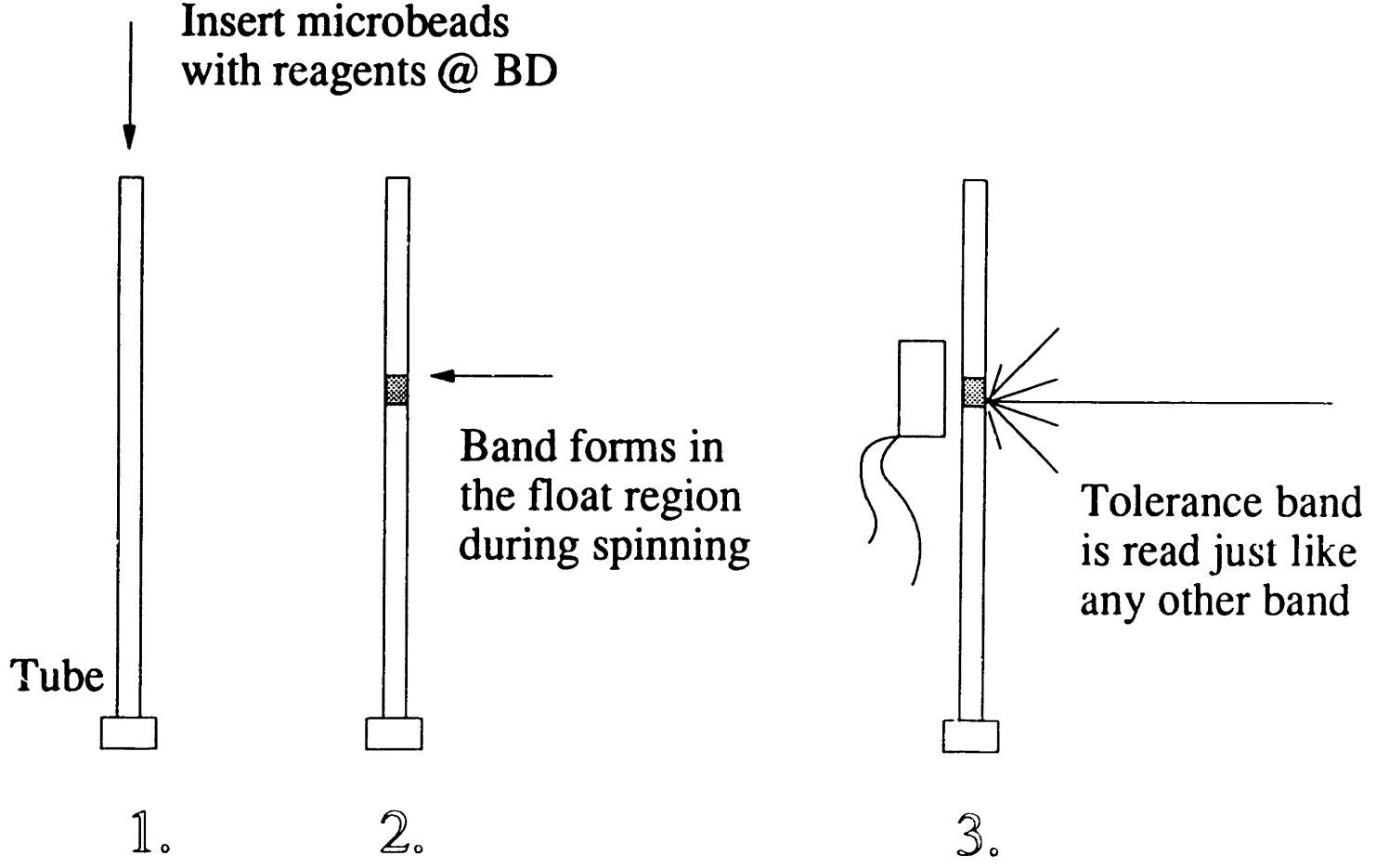
Tube Rotation



Tube Rotation Disk



Determination of Expansion Factor and Calibration of Fluorescense

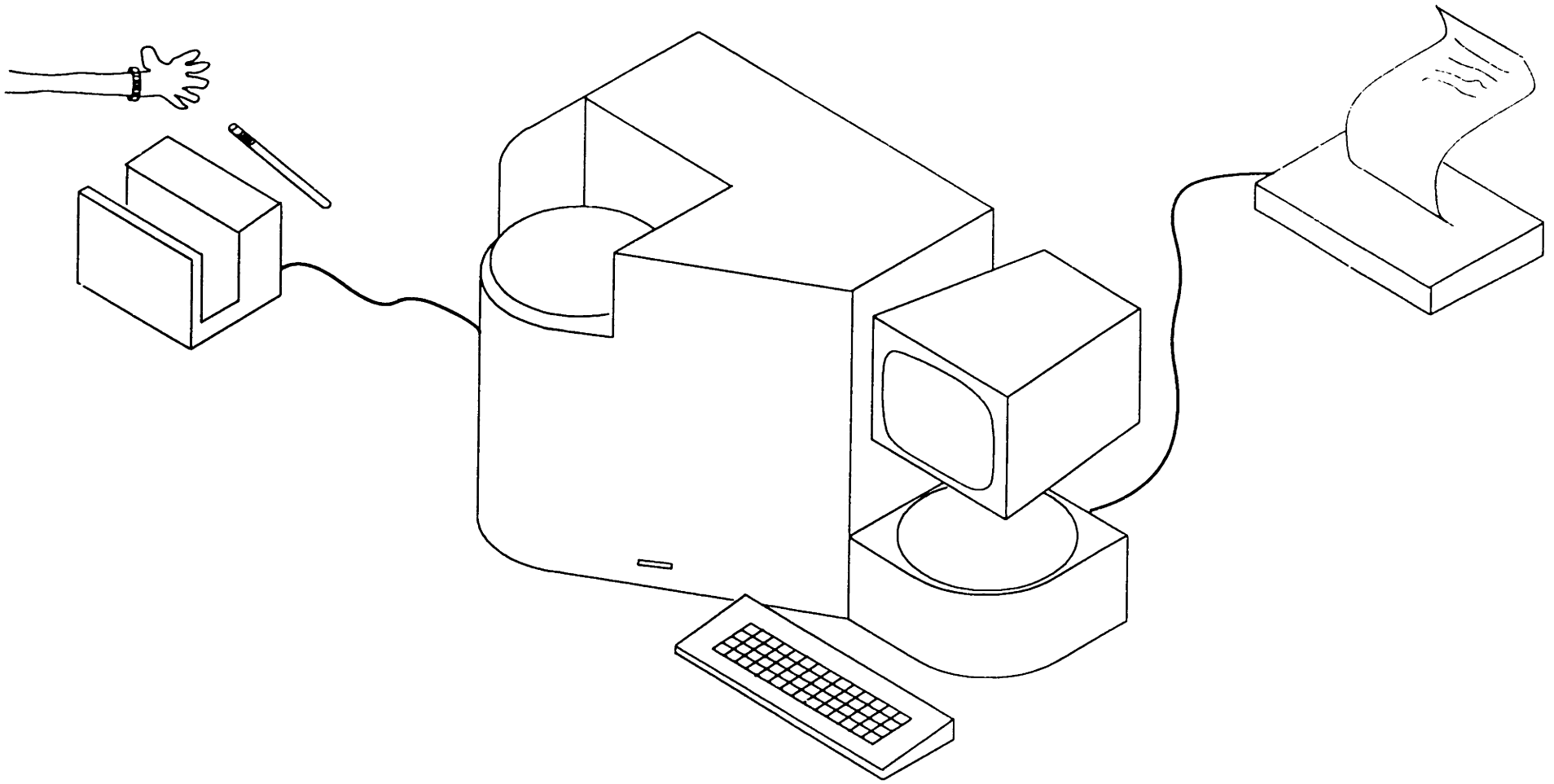


"Dual Rotor"

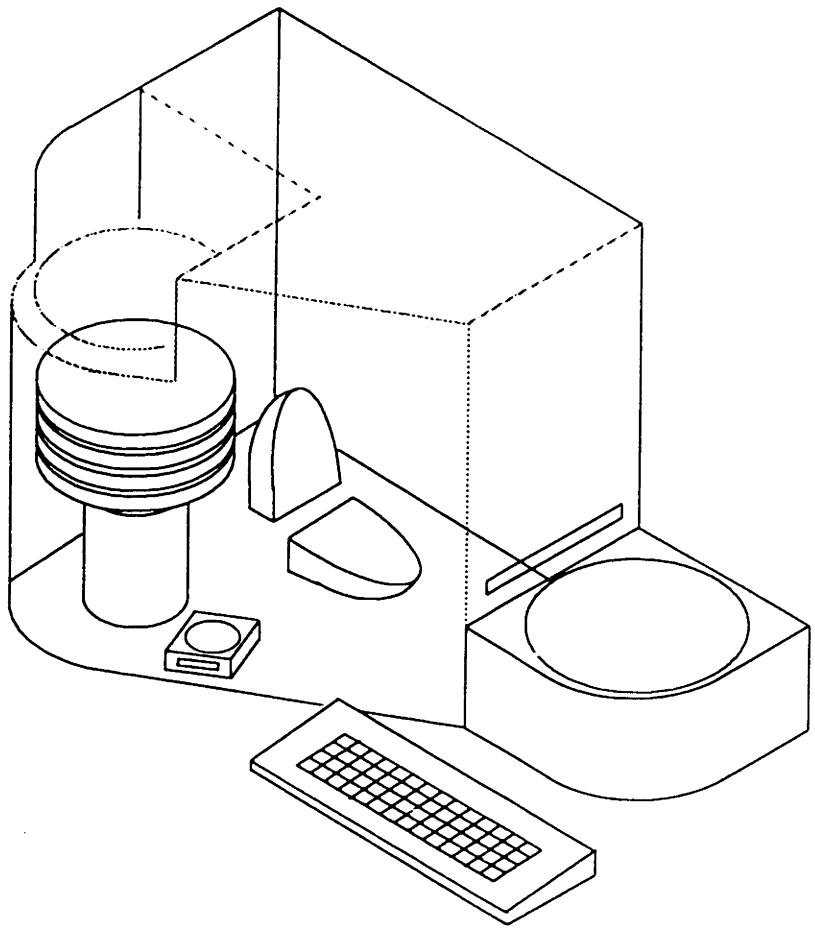
- Walkaway Operation
- High Performance Reading
- Low Sample Time
- Stat Capability
- Batch Capability
- Stores QC Information

"JUKEBOX"

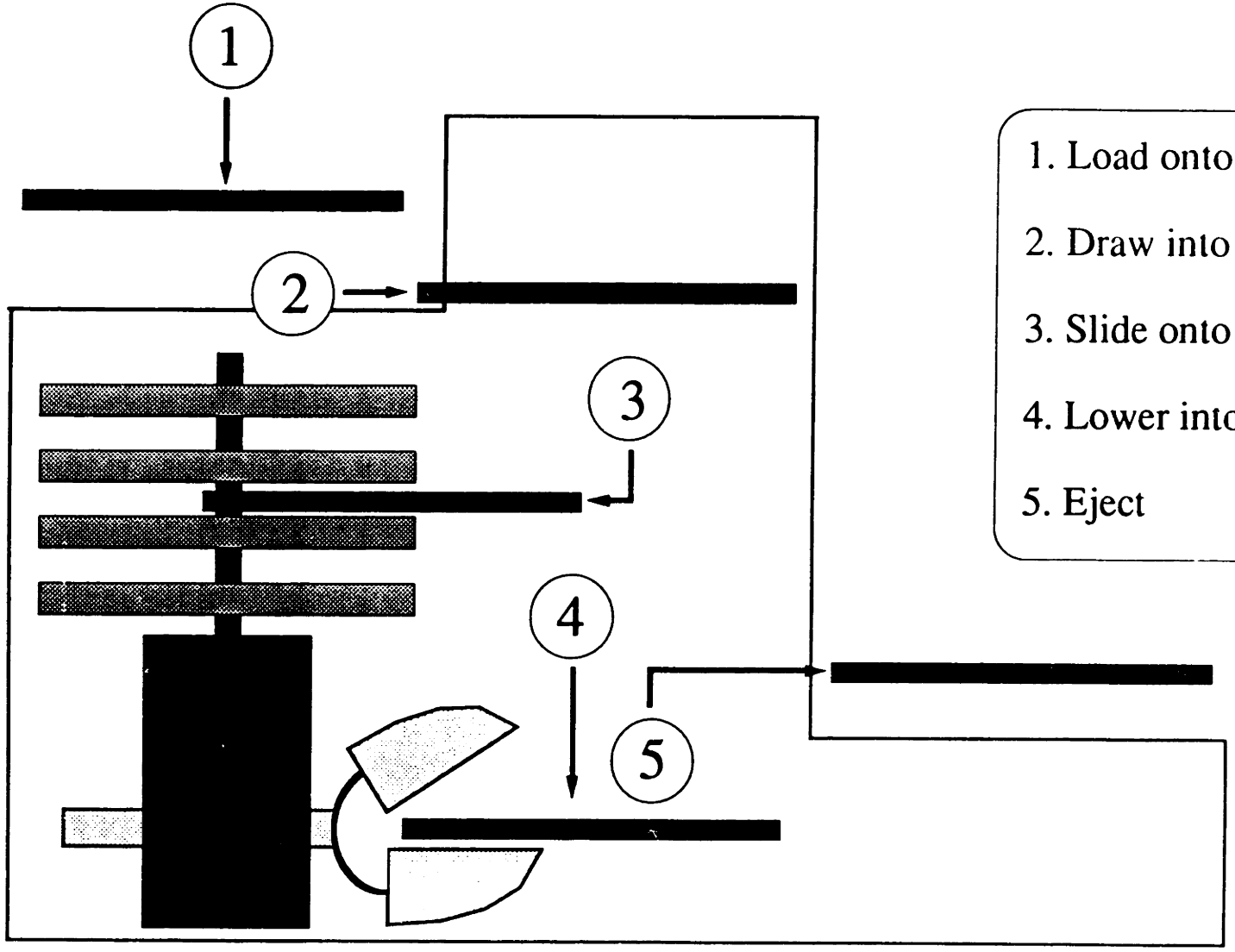
QBC Walkaway from User's Point of View



Cutaway of QBC Walkaway

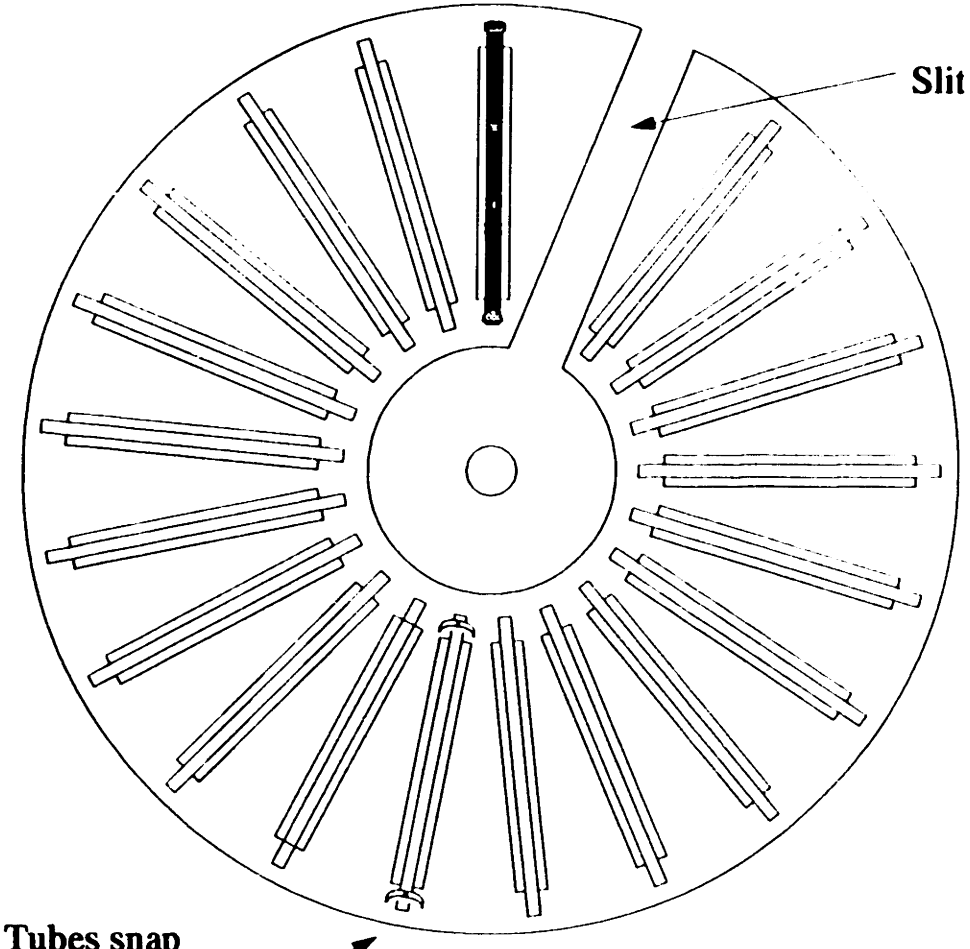


Path of Carousel through QBC Walkaway



1. Load onto stack
2. Draw into QBC
3. Slide onto empty rotor
4. Lower into scanner
5. Eject

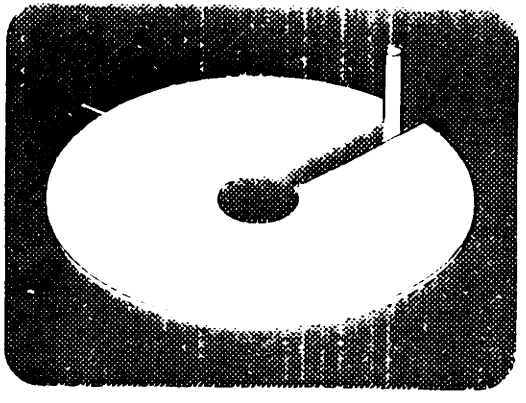
Juke Box Centrifuge Tray



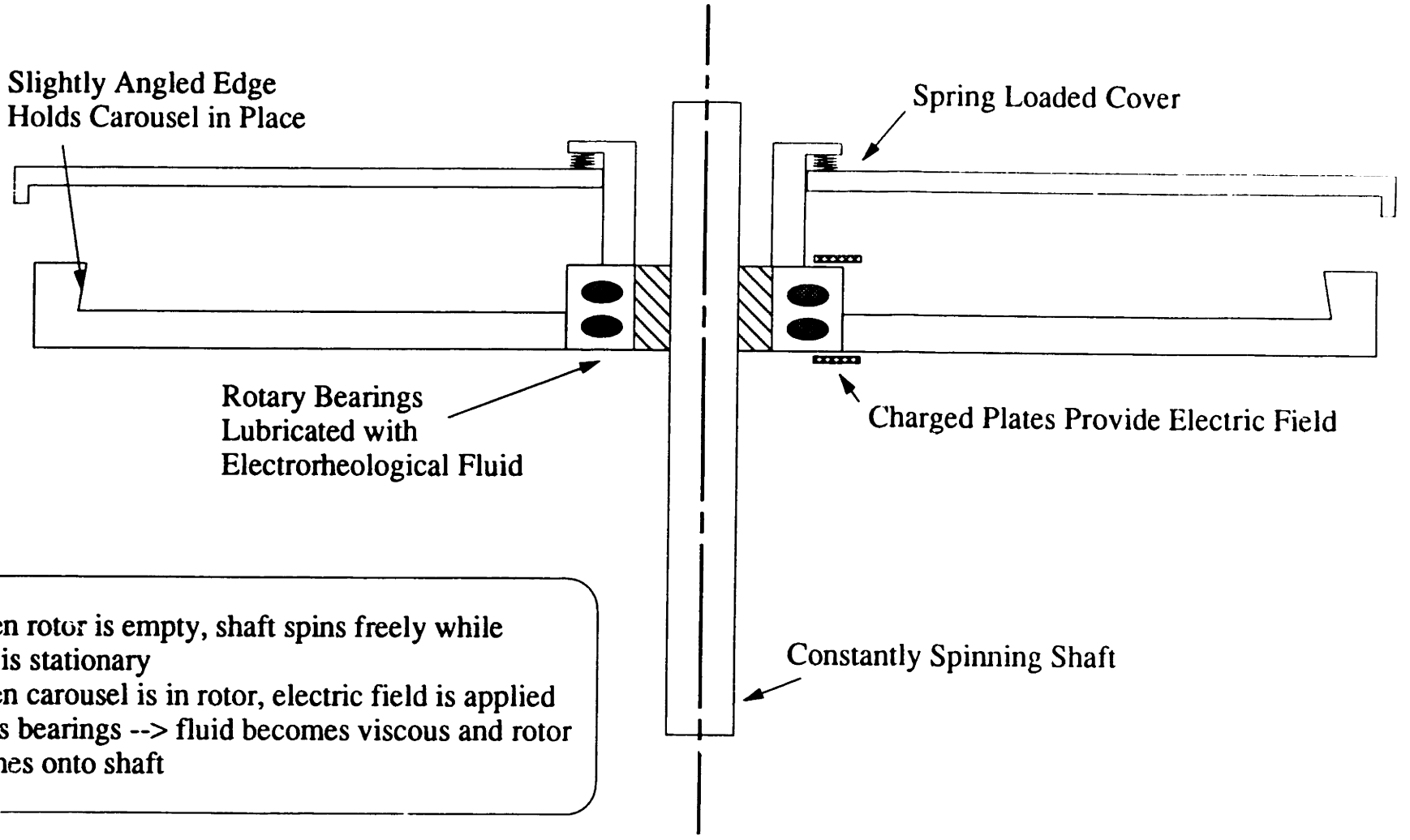
Slit to clear motor shaft

Slots for scanning bands

Tubes snap
securely into place

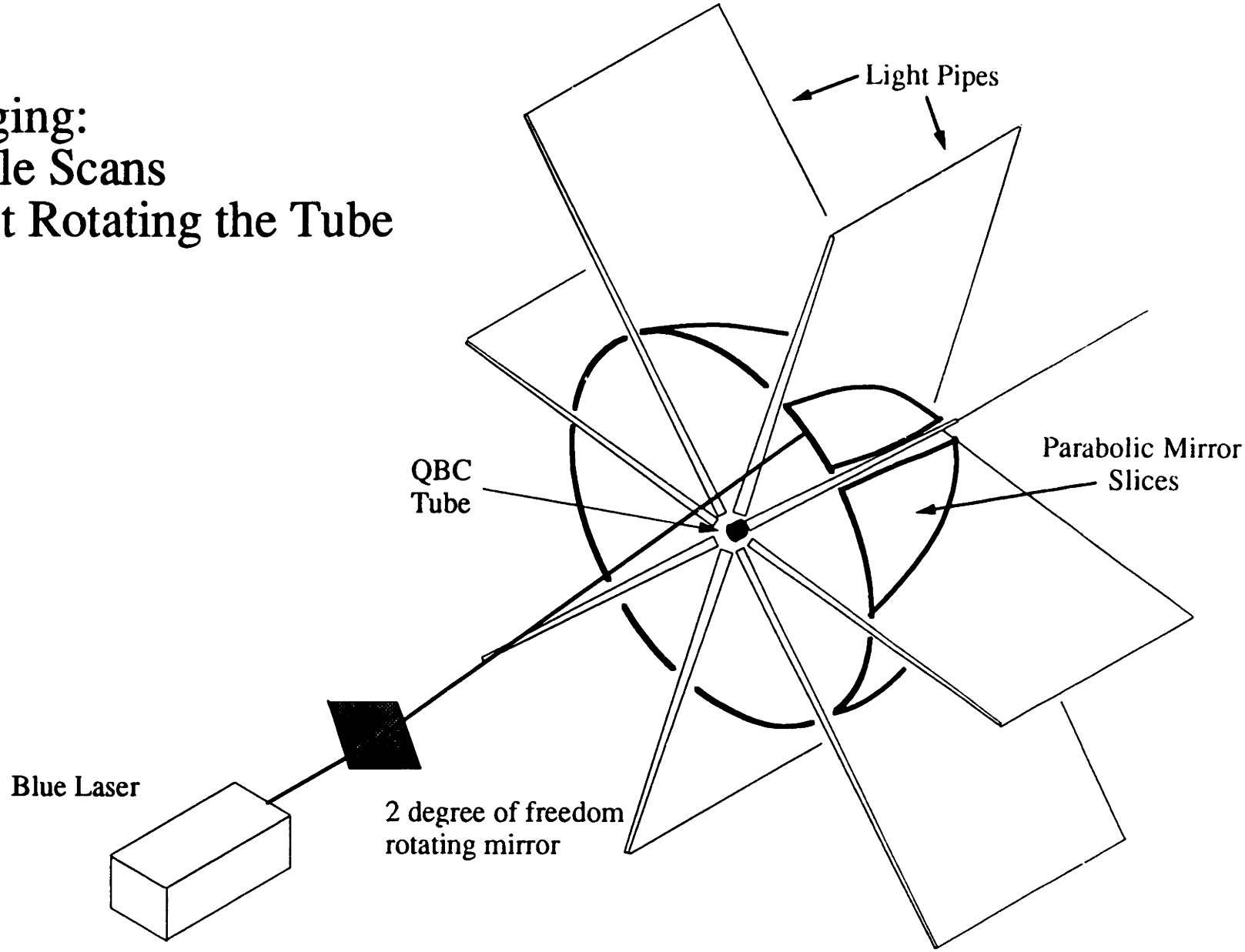


Cross-Section of "Juke Box" Centrifuge Rotor

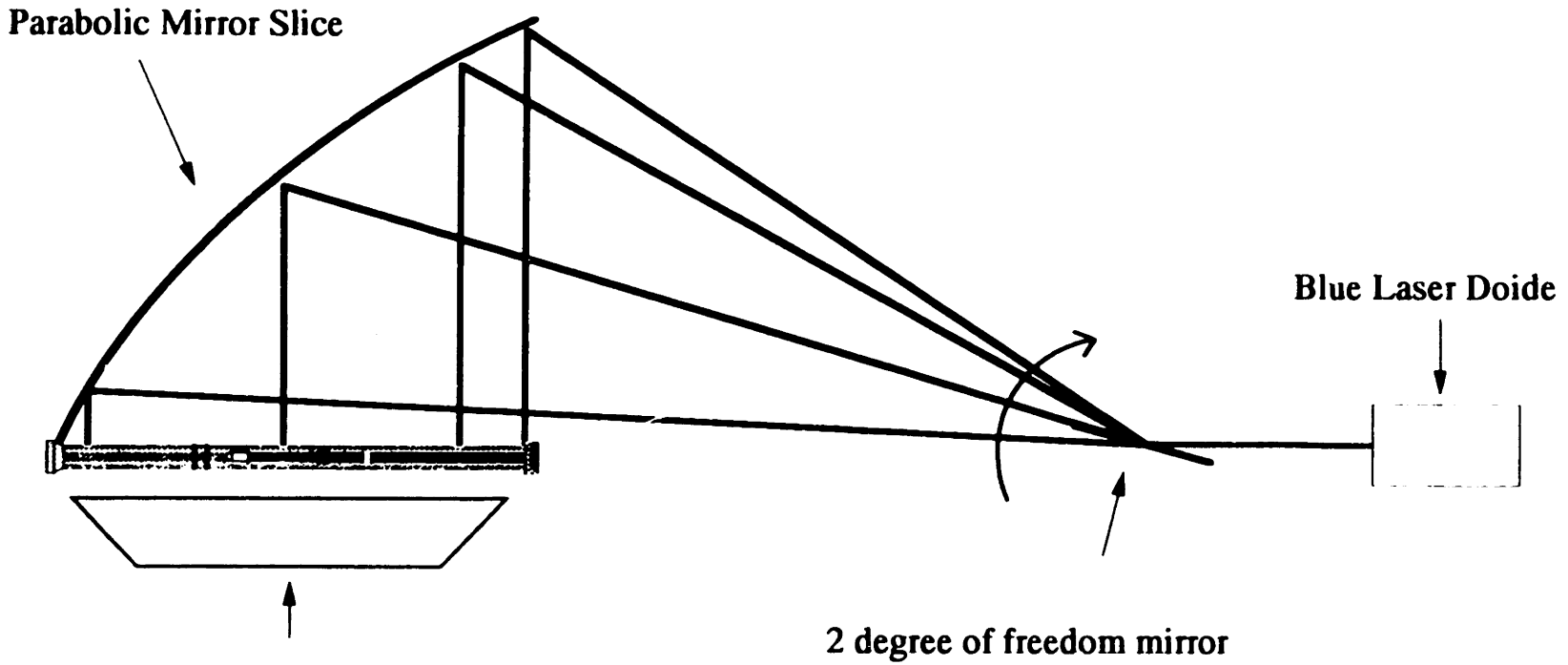


- when rotor is empty, shaft spins freely while rotor is stationary
- when carousel is in rotor, electric field is applied across bearings --> fluid becomes viscous and rotor clutches onto shaft

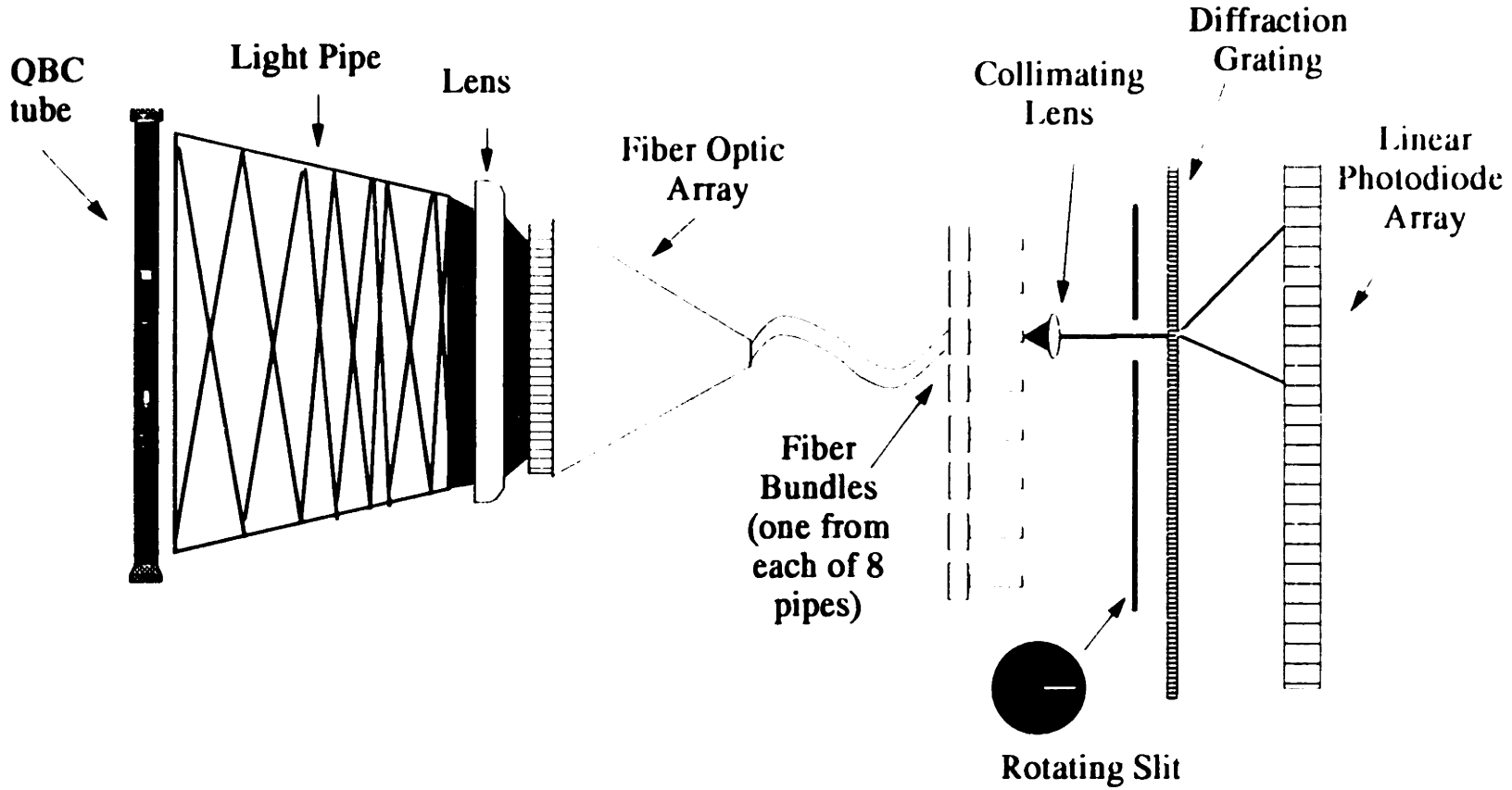
Averaging: Multiple Scans without Rotating the Tube



Path of Light from Laser to QBC Tube



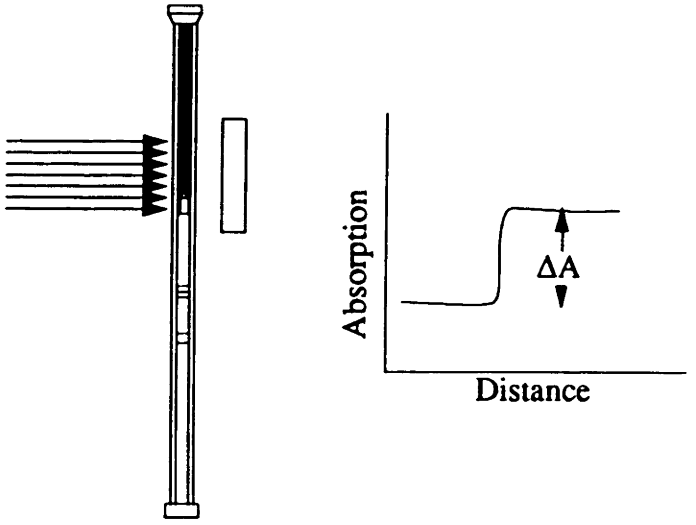
Path of Light from QBC tube to Detector



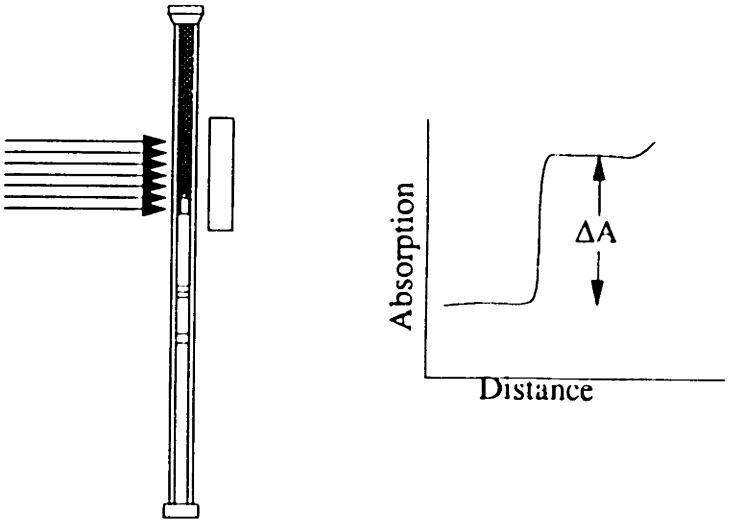
Diffraction Grating + Photodiode Array =
Intensity and Color Information

Measuring Tolerances:
method patented by Levine & Wardlaw

1. On tube of know dimensions, shine light through plasma section and measure change in absorption between float and non-float regions



2. Measure same change in absoption on subsequnet tubes and derive expansion factor from comparison to refernece tube



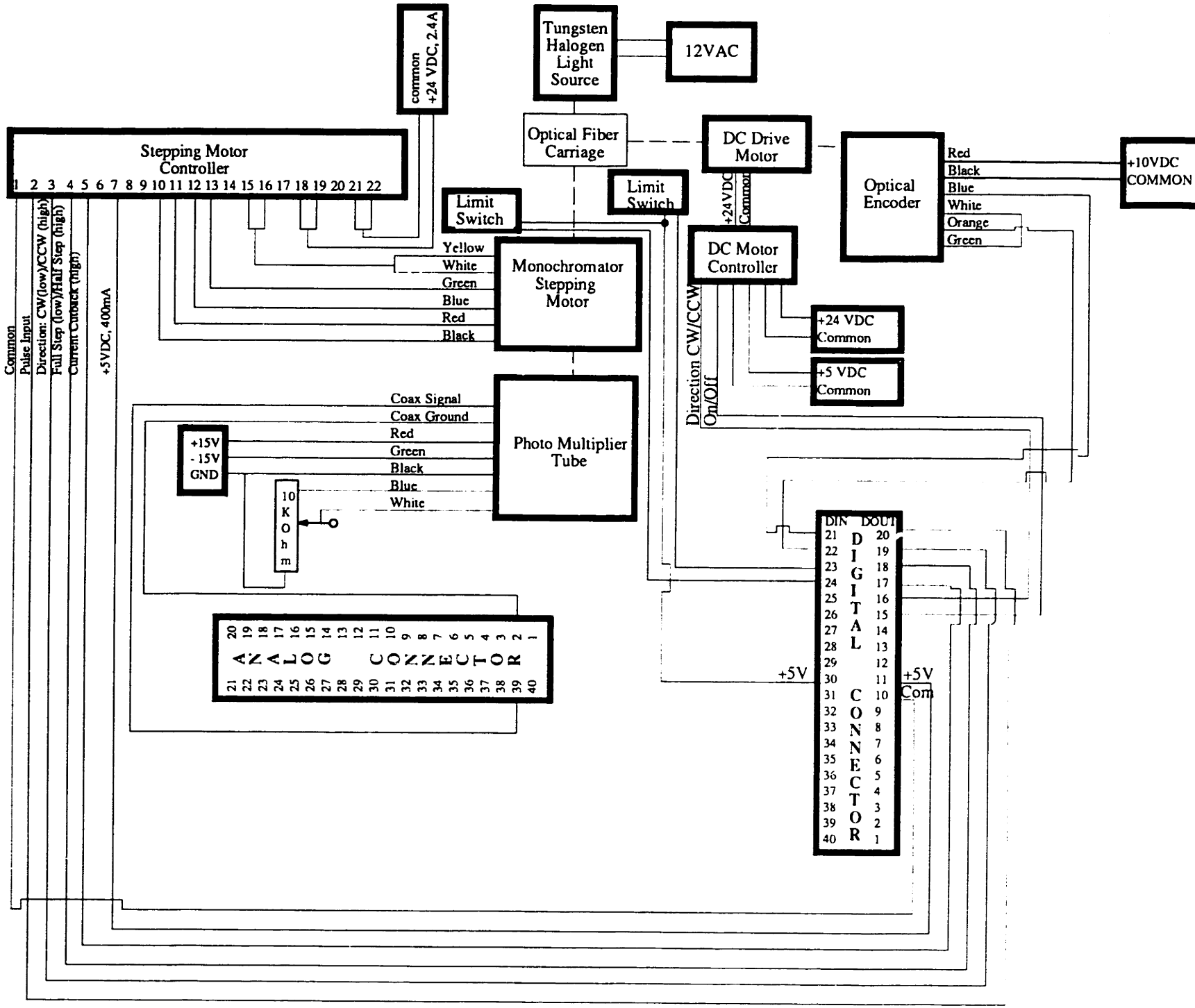
"Juke Box"

Designed to best meet top customer requirements:

- excellent throughput:
  80 tubes in 13 minutes
- walkaway capability
  load 4 carousel at once
- stat capability
- stores and interprets QC information

Appendix F

"Fiber Scan" Schematic Diagram


common
+24 VDC, 2.4A
Tungsten Halogen Light Source
12VAC
Stepping Motor Controller
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
Optical Fiber Carriage
DC Drive Motor
Optical Encoder
Red
Black
Blue
White
Orange
Green
+10VDC COMMON
Limit Switch
Limit Switch
+24VDC
Common
Yellow
White
Green
Blue
Red
Black
Monochromator Stepping Motor
DC Motor Controller
+24 VDC Common
+5 VDC Common
Direction CW/CCW
On/Off
Common
Pulse Input
Direction: CW(low)/CCW (high)
Full Step (low)/Half Step (high)
Current Cutback (high)
+5VDC, 400mA
Coax Signal
Coax Ground
Red
Green
Black
Blue
White
Photo Multiplier Tube
+15V
- 15V
GND
10 K Ohm
ANALOG CONNECTOR
21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40
20 19 18 17 16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1
DIN
DOUT
DIGITAL CONNECTOR
21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40
20 19 18 17 16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1
+5V
+5V
Com

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Footnotes

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