THE CLINICAL ENGINEER; THE OBSERVED NEED, AND PROPOSED ROLE

A REPORT

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES AND RESEARCH
IN PARTIAL FULFILMENT OF THE REQUIREMENTS OF
A MASTER OF ENGINEERING DEGREE

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19 April 1982
For the past few decades, and for the next few decades to come, the amount of high technology equipment used in hospitals has been increasing drastically. This has forced Hospital Administrations to re-examine techniques used to oversee the operation of such apparatus in the hospital, and the scientific principles they use. Different methods are available today for this purpose, from which administrators can choose. The suggested method by this report is the implementation by the Health Care System of Clinical Engineers.

The material in this report is presented in such a manner as to reveal the different aspects related to the position of Clinical Engineering. The report therefore defines the position of Clinical Engineering, the qualifications of a candidate for that position, and describe the observed need for such personnel in the Canadian Health Care System. It also compares Clinical Engineering, as a form of instrumentation management, to the other available methods.

In complying with the Master of Engineering Degree in
Clinical Engineering, the report is also written to give an indication of the qualifications of the author as a candidate for the degree in Clinical Engineering. It attempts to show the competence of the student as an engineer as well as display his knowledge of the clinical environment.
ACKNOWLEDGEMENT

The author wishes to acknowledge the time and effort given him throughout the duration of the degree by his supervisors, Dr. K. Takaya and Dr. W. Silver. He also acknowledges with a great deal of gratitude the assistance he was given by the staffs of the University Hospital, Plains Health Center, Pasqua Hospital, and Regina General Hospital. Finally, the author wishes to express deepest thanks to; Mr. D. Hall, Mrs. V. Mitura, and a special thanks to Mr. R. Mitura for proof reading this report. The author would now then like to formally submit the following as the final report for the Masters of Engineering Degree in Clinical Engineering.
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1. INTRODUCTION

When confronted with such medically associated terms as C/T scan, defibrillator, X-rays or Multi-channel auto-analyzer, the general public is usually at a loss. When encountering problems with these instruments of medicine, the medical staff itself may possibly encounter difficulties. Hence, a need in the hospital may be defined for some specialized person with experience in the operating principles of these devices. This need has been especially prompted by the current complexity of the technology now used in hospitals.[32]

The above mentioned equipment has been presented to the health care industry through the advancements made by technology. The use of high level technology by hospitals has become an ever increasing practice. The modern hospital then has had to contend with the rapidly changing area of medical instrumentation as best it can. These concerns include the teaching of the operating principles to the staff and the overall maintenance of the equipment.[32]

In the past, the aspect of medicine concerned with the instrumentation was a relatively simple task. As the equipment was quite basic, the only problem that arose was the need to make minor repairs or adjustments. This job was easily done then by technicians and maintenance personnel, or even a technically minded administrator or doctor.[8] However, the complexity of the equipment used has increased tremendously. Today, such personnel
would probably have trouble applying power to the devices, let alone repairing it or even describing how it works. Alternative processes have had to be employed to fulfill this need.

An alternative often used to oversee medical instrumentation is a procedure known as a service contract. By this process, the companies selling the equipment give initial instruction on their use, and perform any required maintenance on them. Problems are seen to exist in that the distance between the hospital with its inoperative equipment, and the company office with their service engineers is usually large. Additionally, with the companies employing small service departments, the waiting time by the hospital for a service person to be available could also be large. The net result of this method of instrument teaching and maintenance is that the hospital can incur a large "down time" with its equipment.

The more recent trend in the attempt to solve this dilemma is to have an "in-house" service, teaching, and device evaluation staff, all rolled into one. Composed of technologists and headed by an engineer, the creation of this department in many modern hospitals has been in an attempt to control the operation and functional status of the equipment used. Since the head of the department, the engineer, is responsible for the condition, status, and operation of all the medical instrumentation used, the knowledge and training of this person must be extensive.

The following report attempts to outline some of the training
that is necessary for the position, as prescribed for the degree in Clinical Engineering. The first major section outlines the operating principles of the many varied branches of medicine with which the engineer must be familiar. An indication of some of the various pieces of equipment that a Clinical Engineer must be prepared to work on in research medicine and conventional medicine is given. The second major section of the report gives a summary of several cases where the need for a Clinical Engineer was apparent during this training period. Specifically, this shows how the student applied his engineering abilities in an attempt to better the operation of some of the departments.

To begin this report, a definition of the Clinical Engineer and his responsibilities to the Health Care Industry will be presented.
2. DEFINING THE CLINICAL ENGINEER

There is a requirement for qualified personnel to manage instrumentation in the modern hospitals. The need for these "technically orientated" individuals became apparent during the internship at various hospitals. The problem now exists to define exactly what this position involves, and who is going to fill it.

The proposed job encompasses the applying of scientific principles to different practical applications in the hospital, or by definition, the practicing of engineering. The applications involved here are for a clinical or hospital environment. It is easy then to create a name for this position based on the above two facts about the overall job description. The name applied to this position in the health care industry is that of Clinical Engineer.

In this country, it should be realized that the recognition of the need for Clinical Engineers is quite recent. Thus, all the responsibilities cannot possibly have been fully defined yet. However, it is apparent that any person, or persons, who are to be held responsible for all the considerations which must be given to the area of medical instrumentation in a hospital, will require many diverse personal abilities and qualities. Some of the responsibilities of the Clinical Engineer have been proposed, and many of the necessary qualities can be readily recognized. It is now proposed that these factors concerning the position of Clinical Engineers be discussed.
2.1 Qualities of a Clinical Engineer

Due to the inter-disciplinary nature of the position of Clinical Engineers, the personal traits of the individual play a large part in their success. As mentioned, some of these traits are easily recognizable, but others, are not as apparently important. From the internship on which this report is based, the most important of these necessary characteristics are as follows:

1. To interact effectively with medical personnel, a Clinical Engineer is first and most importantly going to have to be very competent in the field of medicine and with medical terms. This is necessary as in order to be of any value to the medical staff, the engineer must first be able to understand them.

2. To deal with the demands of the overseeing of a hospital's biomedical instrumentation needs, this person must be technically knowledgeable. This will include competence in the fields of electronics, mechanics, and other applied sciences, as well as be familiar with the safety requirements of the clinical environment. Such knowledge will become especially important when a person is required to extend consultation as a member of a medical research team.

3. This position is also going to require a person with an administrative background. This will be due to the requirement of the individual to be responsible for evaluating the needs of different pieces of equipment. As well, he will be responsible for supervising the general operation of the Biomedical Department in the hospital. This will require administrative decisions such as the hiring and firing of the technical staff for the proposed Biomedical Department. Additionally, the budgeting of the same department will fall upon the shoulders of the same person.

4. A person filling the above mentioned position will need to be capable of communicating exceptionally well. The individual will be required to teach to the different hospital staff about the equipment, and ensure they understand so there is no violation of operating procedures. This ability is a basic necessity.
5. There is the requirement that the Clinical Engineer have excellent interpersonal skills. As mentioned before, this is due to a person having to deal with most areas of the hospital. Such a scope would include janitors, technologists, doctors, and possibly even physicists. Therefore, this position requires a person able to exist harmoniously with all these people and their varied backgrounds.

These are the obvious characteristics that Clinical Engineers should have. Undoubtedly, many more exist. However, just as is the case with the responsibilities of the proposed position, enough time has not elapsed for a full and comprehensive list to be compiled. With the responsibilities of the Clinical Engineer though, studies have been done on which a reasonably good list can be proposed.

2.2 Responsibilities of a clinical Engineer

Although some of these "matters" with which the Clinical Engineer must concern himself have been alluded to, they have not formally and fully been discussed. The task is now to define the functions of a Clinical Engineer as they have been described to date.

Perhaps the most adequate presentation of these points has been indicated in the report presented to the Canadian Committee for Hospital Accreditation by the Canadian Medical And Biological Engineering Society. From the seven basic principles for hospital accreditation suggested by this task force, seven responsibilities for the Clinical Engineer can be summarized as follows:[14].
1. The Clinical Engineer will reside in a base hospital where he will work with physicians, nurses, administration, and allied health personnel directly upon problems of concern in patient care and hospital services.

2. The Clinical Engineer would be associated with the management of medical technology.

3. As a teacher, the Clinical Engineer would ensure that the hospital has an appropriate range of educational programs that ensure that medical technology will be used safely and effectively.

4. The hospitals, through the Clinical Engineer, would have an appropriate system for reporting and investigating incidents which involve medical technology.

5. It should be the Clinical Engineers' responsibility for setting up a system for registering and assessing all medical device alerts, received from external sources or hospital staff, and for assuring that appropriate remedial action is taken promptly when warranted.

6. Through the Clinical Engineering Departments, all incoming equipment should be checked for safety and compliance with pertinent standards. Then, by placing an acceptance notification on the instrument, the responsibility for that device should be taken on by this department, and specifically, by the Clinical Engineer.

7. A Preventative Maintenance program for all (medical) instrumentation should be set up, and enforced, by the Clinical Engineer. This program would include: a regularly scheduled inspection of the equipment to determine if the equipment and its facilities comply with the relevant standards and regulations.

These seven points indicate that the job of being a Clinical Engineer is quite an involved one. Indeed, it may be questioned if all of these responsibilities need be accepted at by this individual. Again, based on observations during the previously mentioned internship for which this report is written, the need
does exist for someone to be responsible. Some of these observations will be outlined later in the report.

From the above points, it becomes apparent that the primary function of the Clinical Engineer will be to act as an interface between technology and medicine. It is also quite apparent that a basic knowledge of medicine is required by that person.

Now that the criteria suggested as being necessary for the Clinical Engineer to function in the hospital have been stated, the question arises as to how one actually obtains the title of a Clinical Engineer. That is, what education is necessary to allow an individual to fill this position?

2.3 Requirements for a Clinical Engineer

With the function of a Clinical Engineer defined, and some of the necessary qualities referenced, the question now is, "is an engineer fresh out of university with a Bachelors degree, capable of fulfilling all these functions'? In fact, is he even capable of comprehending the reasons for their being? The answer to this question is no, as seen by the Canadian Medical And Biological Engineering Society, a body which now certifies Clinical Engineers.

In the paper, "Clinical Engineering and Hospital Accreditation in Canada", presented by Mr. J. McEwan at the 23 C.M.B.E.S. Conference, the minimum requirements suggested necessary to fulfill the definition of a Clinical Engineer are fulfillment of
either one of the two following:

1. Registration with a provincial professional engineering association, a Masters' degree with specialization in biomedical or clinical engineering, and two years pertinent experience.

2. Registration with a professional engineering association, and a minimum of three years pertinent experience.

It is the first of these two alternatives which this report is most concerned with. Specifically, this involves the degree in Clinical Engineering as a route to becoming a certified Clinical Engineer.

Similar to other Masters' degrees, the study in Clinical Engineering requires a portion of its entire duration be spent doing course work. The courses would pertain to Biomedical Engineering, with more emphasis on the medical side so that the student begins to see how engineering is applied in the hospital (Appendix I).

With the course work to his credit, the degree as given at the University of Saskatchewan, requires the student spend at least six months in the clinical environment. The distribution of the time spent in this portion of the degree, department wise, is as shown in Appendix II. As can be seen, such an experience would give the student an extremely good introduction into the operation of a hospital. Additionally, this work experience could be applied to the suggested two years "pertinent experience" required for certification.
One other very important way this format for the Clinical Engineering degree prepares the student for certification is by having the student exposed to some poor engineering practices in the hospital. Finally, by some department directors, the students are encouraged to apply their engineering skills in an attempt to design, or modify, some aspect of the department that the director recognized as being inefficient. This provided exposure for the student to one of the needs in the hospital in the hospital for a Clinical Engineer.

Primarily however, the single important aspect presented by this degree program to the student, looking at it in retrospect, is to provide him with an introduction to the many varied operating procedures used in the hospital. This also included allowing him to observe the operation in the clinical environment of many of the pieces of equipment that he will be concerned as a Clinical Engineer. The program then, as a whole, gives to the student an indication of the need of Clinical Engineers in the hospital.
3. HOSPITAL PRINCIPLES AND INSTRUMENTS OF CLINICAL ENGINEERING

CONCERN

The hospital is an institution which abounds in a large amount of high technology equipment. Because of this equipment, certain considerations have to be made by the administration as to its maintenance and other associated aspects. It is suggested that this area of the hospitals' operation be the responsibility of a Clinical Engineer.

In order to justify such a suggestion, the following points should be noted. Firstly, there is an extremely large amount of high technology equipment in the hospitals today. Also, the equipment used in the hospital is changing exponentially, both in sheer amounts as well as complexity. Therefore, a person such as a Clinical Engineer could be given the task of maintaining the hospital equipment, in addition to the other equipment related aspects pointed out in the preceding chapter. This need of expertise in the hospital was amply apparent throughout the internship. It is noted that from these hospital rotations the material for this report was obtained.

The eight month hospital internship was performed as per the requirements of the Clinical Engineering Degree at the University of Saskatchewan. The intended purpose of the internship was to introduce the student to the everyday practices of the hospital. It also served to point out the need of such a suggested position as a Clinical Engineer.
The primary training site for the medical aspects of the degree were carried out at teaching hospital of some 540 beds, located in the province of Saskatchewan. Additionally though, material for this report was gained through time spent in three other health care centers. The format for the internship as pointed out in Chapter One, required an interaction with several different hospital departments. The students were required to spend a period of time in several of the different departments in the hospital. As a result, they gained an exposure to the many different operating principles and equipment incorporated in the health field.

From the rotations throughout the hospital, many varied pieces of equipment were observed. It is intended in this chapter to indicate some of the operating principles used in a large health care institute.

Referring to Appendix II, a breakdown of the departments interned at is given. Following this outline, the discussion of the different equipment and operating principles used by the departments visited will commence with a consideration of the 'modus operandi' of the Pulmonary Medicine Department.

3.1 Pulmonary Medicine

In the department of Pulmonary Medicine, the main priorities were understood to be involved with the lungs. This then involves the search for lung disorders or malfunctions. In the department, emphasis can additionally include work done in the form of
research or clinical treatment. In either case, this involves looking for such diseases as emphysema, asthma, and other restrictive or obstructive lung diseases. Furthermore, the Pulmonary Medicine Department may be actively involved in the attempt to cure these diseases. This is by performing research experiments into the causes and the effects of everyday stimuli on patients with these pulmonary problems. The equipment found in this department is that aimed at obtaining physical measurements about the lungs operation. From these, a diagnosis can then be made on the physiological condition of the lungs and the associated Pulmonary system.

Of the actual parameters that are measured in order to allow for the diagnosis of the different diseases, basically all stem from two main variables, pressures and volumes.[24] Additional parameters that are measured though are flows, temperatures, and rates or frequencies. From these values the physician is presented with data with which, along with some mathematical relationships, he is able to determine the state of the lung and its associated pulmonary circulatory system. It is acknowledged that although a major paper could be written on the correlation of the physical data measured, of primary concern to this report is the equipment and operating principles used by the department, rather than the resultant diagnosis.

3.1.1 Spirometer

One of the pieces of equipment still used in many respiratory
labs is a spirometer. Shown in Figure 3.1, this is seen to be a
displacement bell chamber floating in a water tank. The physical
construction of the instrument has the bell chamber connected to
a counterbalance via a chain and pulley. On the counterbalance is
mounted a pointer which is used to indicate a calibrated
volumetric movement. Connecting a mouthpiece to the bell chamber,
as shown in the diagram of Figure 3.1, is a flexible piece of
tubing. Hence, when the patient breathes in and out of the
mouthpiece, the bell chamber is forced upwards or downward,
depending on the volume breathed. Therefore the pointer is also
forced to move in response to the breathing of the patient, and
thus permits quantitations of several pulmonary parameters.[24]
Such an arrangement allows for any volume of expired air by a
patient to be registered as a displacement of the chamber in a
vertical direction. In essence, the spirometer is a respiratory
volumetric measuring device.

Due to the fact that any lung volume expired by the patient
will cause movement of the chamber, the physician can use these
calibrated movements as an indication of the lung itself.
Specifically, some of the parameters that can be obtained this
way are Residual Lung Volume, Lung Tidal Capacity, and Functional
Residual Capacity (Figure 3.2).

Owing to the impossibility of exhaling all the gas from the
lungs, it is realized that certain measurements cannot be made
with the spirometer. Additionally, certain types of measurement
Figure 3-1: The Spirometer; A Volume Measuring Device
Figure 3-2: Volumes of the lungs. These variables can usually all be derived from measurements made with the spirometer.
are too cumbersome to obtain from a spirometer trace. An example would be a rate of flow determination. Such variables then are more easily obtained with a pneumotachometer.

3.1.2 Pneumotachometer

The main function of a pneumotachometer is to permit the measure of respiratory gas flow. By acting as a transducer (see Figure 3.3) its operation is based on the pneumatic equivalent of ohms law. That is:

![Diagram of Pneumotachometer](image)

**Figure 3-3**: The Pneumotachometer; A Rate Measuring Device
\[ E \text{ (difference in pressure)} = \frac{I(\text{Flow})}{R \text{ (fixed resistance of pneumotachometer)}} \]

Drawing an analogy between a resistor in an electrical circuit and the pneumotachometer, the operation of a pneumotachometer can be easily explained. The apparatus operates by having the patients' air blown through it. Just as an electrical current passes through a resistor, some voltage, or pressure in this case, is dropped across the device. It is this pressure differential, transduced by a differential transformer or other such transducer, that is measured. Therefore, the faster the flow, the greater the pressure differential produced.[24]

There are a number of specific considerations that must be made before the basic pneumotachometer can be used for pulmonary measurements. One such consideration is that exhaled air is saturated. If uncompensated for, this moisture could become condensed in the pneumotachometer causing partial obstruction to the ducts in the baffle plates. Hence, when being used for pulmonary measurements, the pneumotachometer is usually equipped with a heater element to prevent the condensation of the exhaled air.

A second major requirement of the pneumotachometers' design is that it must have linear or nearly linear resistance over a wide range of air flows. The baffle duct design then is critical since if the system is restrictive, it will influence the pulmonary work load. These two considerations are the major ones that must
be given the design of a pneumotachometer.

Repeating the main function of the above process, the use of a pneumotachometer presents a physician with the respiratory air flow for the patient. With this information a diagnosis of several diseases can be made.

3.1.3 Pulmonary function computer

An advancement in the Pulmonary Medicine field which also measures the flows and volumes as well as other important parameters, is the Pulmonary function computer (Figure 3.4). The parameters are obtained by the computer being connected directly to the pneumotachometer. Hence, data is collected instantaneously and stored. After the data has been collected, the computer goes back and uses this data to calculate other important pulmonary parameters.

A useful feature of the function computer is it readily interfaces with a mass storage device. This aspect is most useful for the filing of the acquired data. This allows for rapid recall of any desired data.

3.1.4 Respiratory technology

The final area associated with Pulmonary medicine is Respiratory Technology. The main function of this department is to oversee the operation of the respiratory assist machines, the respirators. This is noted to be a major area of medicine as it involves patients in the intensive care units. These pieces of
Figure 3-4: The Pulmonary Function Computer. Combining the pneumotach with the modern computer technology, the system has a differential pressure read into the computer, where it is combined with other environment parameters to describe some function of the lung. The result is then stored in the computer’s memory.
equipment are often used for critically ill patients who are not able to breathe on their own.

To provide assistance to the patient, the respirators used have three modes of operation. The first is the assist mode, where the machine detects a decrease in pressure in the wind passage, and subsequently provides the positive pressure required to force the air into the lungs. A second mode of operation is referred to as control. Here the respiration rate, volume and pressure is maintained automatically by initial settings made by the respiratory technologist. The final mode of operation is a combination of these other two. Hence, an assist is given by the respirator only if a certain pressure in the air pipe of the patient is not met. In addition to these modes of operation, the device also has provision for sounding an alarm should any of the afore mentioned settings be exceeded.[25]

The area of Pulmonary Medicine can be closely associated with the department of Anesthesia due to the department of Respiratory Technology. Both departments are involved with patients that are in critical condition, and thus may require some sort of breathing assistance.

3.2 Anesthesiology

The field of Anesthesiology is a good example of how technology has had a major influence on the medical field. The field has advanced from the days when an ether soaked rag was the only anesthetic given, to one where concepts from many different
disciplines of science are used. This culmination of the disciplines has resulted in advancements such as patient ventilation which is automated, to pressure monitoring that is more reliable. It has also developed systems designed specifically to aid the Anesthetist monitor the effects of medication, as well as the general condition of the patient. It is pointed out, however, that much of conventional Anesthesiology is still concerned with the drugs (anesthetic) and the attempt to relieve pain during surgical operations performed on the patients.

3.2.1 Anesthesia machine

Of primary concern to the Anesthetist is the respiration of the patient. It is well known that some drugs required by the patient in an operation cause a reduction in the respiration rate to a dangerous level. To counteract this problem, the Anesthesia machine is used (Figure 3.5). Acting as a normal respirator, this device has the capability of force ventilating the patient at set rates and volumes. This is done by the method described above with the respirator operating in the controller mode.

Besides acting to assist the respiratory ability of the patient, the Anesthetic machine also provides a means for the anesthetic gases to be supplied in controlled proportions. This is in fact the area that the most recent advances in the anesthetic machines has occurred. It is noted that some of the gases used by the Anesthetist such as Nitrous Oxide and
Figure 3-5: The Anesthetic machine. This instrument is used both to provide artificial respiration during an operation, as well as a means of administering some of the anesthetics.
Oxygen are compressed and stored in cylinders. The concentrations of these gases in the outflow of the machine can therefore be accurately controlled by flowmeters and needle valves. Other of the agents used by the department, such as halothane need to be vaporized however before it can be included in the administered gas. The method used to do this is to disperse a stream of oxygen through the anesthetic liquid. The maximal liquid-gas interface then provides an outflow consisting of oxygen saturated with the anesthetic vapor. The amount of vapor added to the other gases from the machine is readily controlled by the needle valve and flow meter in the line supplying the oxygen for vaporization.

3.2.2 Oxygen monitor

Associated with the above apparatus is an oxygen monitor, which has the responsibility of reassuring a certain oxygen gas level. The operating principles of this device will be covered in the next chapter. The main objective of such a device is to ensure that the percentage of oxygen in the air presented to the patient is adequate. An alarm is therefore sounded if the percent oxygen in the gas falls below some preset percentage.

3.2.3 The electrocardiogram monitor

A number of other physiological events are used by the Anesthetist to indicate the state of well being of the patient. One such signal which can be easily monitored is the electrocardiogram (E.C.G.). Hence, a piece of instrumentation
often found accompanying the Anesthetic machine is an E.C.G. monitor. The signal which this instrument is concerned with is acquired from the surface of the patient's chest. In actual fact, it is the electrical signal emitted from the heart itself. The function of the device therefore is to amplify this signal of approximately 1 to 3 millivolts to one of about 1 to 2 volts. The signal is then readily displayed on a cathode ray tube (C.R.T.), or printed out to some permanent storage medium. It was seen for this system that most of the considerations must be given to the acquiring of the signal. Specifically this involves looking at the electrodes used.

Quite simply, the E.C.G. is obtained by picking up the signal off of the patient's chest, via Silver-Silver/Chloride electrodes. As these are non-polarizable electrodes, they find major applications in the monitoring of long term patients. Here, one of the big concerns is the generation of a "half cell potential" over the extended period of time that the patient is monitored. The E.C.G. monitor itself also has provision to sound an alarm, preset to some desired level of sensitivity by the Anesthetist.

The type of alarm most commonly found on an E.C.G. monitor is one which detects abnormalities with respect the rate of the signal. If the signal deviates outside a preset window of permissible rates, the alarm will sound. Hence, should the drugs given by the Anesthetist render the patient in too deep a sleep,
or alternatively, if the patient starts to twitch from the pain of the operation while the operation is still in progress, the Anesthetist can take actions to rectify these problems before they become major. The E.C.G. as a signal is therefore used by the Anesthetist to indicate the effects of some administered medications, as well as the general well being of the patient.

3.2.4 Temperature and pressure measurement

Two other important physiological parameters which must be monitored are the patient's temperature and blood pressure. The basic temperature detecting transducer found in the Operating Room is a thermocouple. Mounted on a probe, these thermometers may be specialized in their use, such as a nasal, oral or rectal applications. However, the same physical principles apply to the operation of each.

The set-up is the same for all three orifices, with the probe being inserted in one of the three. The variants detected are in the form of an electrical signal which is scaled and read directly from a Liquid Crystal Display.

In considering the measuring of the blood pressure by some noninvasive method, the old and trusted Sphygmomanometer is almost exclusively used.[24] This is the device which determines the blood pressure through the detection of the Korotkoff sounds. The detection of these sounds is by placing some pressure transducer over a peripheral artery. Then with a tourniquet controlling the blood flow in that artery, the pressure is slowly
released, and the blood allowed to flow through the blood vessel once more. As the pressure is released the Korotkoff sounds can be detected.

In an attempt to make the measuring of blood pressure more automated, a device is now available which applies the required pressure automatically. With the regulated release of the pressure, it detects the Korotkoff sounds and displays both the systolic and diastolic pressures as an output.

The second most commonly used technique for measuring the blood pressure is via an invasive method. When using this procedure, a catheter is passed into the cardiovascular system through a peripheral artery. The catheter, for pressure measurements, is noted to be a fluid filled piece of tubing. Therefore, any pressure acting on the end of the catheter in the cardiovascular system is transferred to the outside of the body, facilitating easier measurement. The exterior end of the catheter then is where the actual transducing takes place. The transducer most often used is a piezoelectric crystal. The drawback to this form of pressure measurement is that it is invasive, necessitating additional consideration be made before the process is undertaken.[24]

3.2.5 Infusion pump

A final device which has been added to the arsenal of the Anesthetist to free his hands, is the infusion pump. The purpose of this instrument is to infuse, at a controlled rate and volume,
the necessary anesthetic fluids. Previously this was done by a
gravity fed "Intravenous Drip". The newer technique uses a roller
bar to administer the calibrated quantities of fluid to the
patient.

These above mentioned pieces of equipment are in daily use,
permitting the Anesthetist to monitor many more of the patients' vital signs. Hence, he is better able to take measures to
alleviate the pain of the patient during an operation. Also, he
is able to recognize and respond to potential or real dangers earlier in their occurrence. The rectification is achieved through a more controlled administration of the drugs used.

Consider now the medical field of Cardiology. Like the Pulmonary Medicine Department, the names applied to this department tend to be quite descriptive of the function of the department. It is also noted, and will be pointed in the following paragraphs, that this area of the hospital in particular, has many allied fields of medicine associated with it.

3.3 Cardiology

By definition, a person associated with this department is concerned with the circulatory system. The circulatory system includes the blood vessels of both the systemic and pulmonary systems, and most importantly, the heart itself. In many hospitals, the tests of radiology, echocardiography, electrocardiography, and the stress test laboratory are all used
in conjunction with hemodynamic tests by the Cardiologist. The result of the combination of these tests is that the physician is better able to diagnose the competence of the Cardiovascular system. It therefore easily understood that the equipment used to aid the Cardiologist obtain his goal is varied and often times complex.

3.3.1 The Hemodynamics lab.

In the Hemodynamics lab, equipment types range from fluoroscopic and angiographic devices to pressure and electrocardiogram monitoring apparatus. The information from this lab tells the physician about the heart's pumping capabilities, as well as the integrity of its blood vessels. Specifically this includes blood pressures within the four main chambers of the heart: detects heart defects such as Patent Ductus Arteriosus, Ventricular-Septal Defects (VSD), and Atrial-Septal Defects (ASD); helps locate infarcted areas of the heart wall; gives measured values of the cardiac output and oxygen saturation of the blood; allows for a fairly reliable diagnosis of the competence of the four heart valves, and finally, permits the doctor to observe the integrity of the coronary arteries.

In order for the lab to produce the above results, a means is required for the doctor to actually get inside the Cardiovascular system. In the Hemodynamics lab this is accomplished via catheterization, or more explicitly, entering percutaneously into a peripheral vein or artery.
Once the catheter, a fluid filled tube, is inside the selected blood vessel, usually the femoral vein or artery, it is advanced along until it enters the right or left side of the heart respectively. Through this tube, the relevant pressures of the heart are transmitted to an external pressure measuring device. Alternatively, to detect the different heart defects, a radio-opaque substance is injected into the proper area of the heart. Aided by cineangiocardiography or fluoroscopy, that part of the heart containing the substance can be imaged. From this image more information such as valve competence, left ventricle volume, and areas of infarcted heart wall can be determined.

A final information gathering technique employed by the lab involves the use of a densitometer. The test is used to determine the cardiac output and also to detect intracardiac shunts. Referred to as the Indicator Dilution Curve Test, the procedure of operation begins by injecting a dye, usually indocyanine green dye, through the catheter into the right side of the heart. Blood from the left side of the heart is then drawn off and tested in the densitometer. The test performed is to detect changes in light transmission of the whole blood produced by the dye. Then from this procedure, a curve similar to that shown in Figure 3.6 can be plotted. From the shape of the curve and the area under the curve, the above hemodynamic information can be determined. [24][19]

The Indicator Dilution Curve test has become the most widely
used method for the estimation of cardiac output.[24] It is also useful in the diagnosis of heart shunts and is acquiring a reputation in the diagnosis of incompetent heart valves.[19] The use of such a technique though requires that the following assumptions be made.[24]

1. Although there is recirculation, it does not occur during a significantly large fraction of the inscription of the curve.

2. Flow and volume are relatively constant between the injection and sampling sites.

3. The distribution of transit times of the indicator is representative of the distribution of transit times of the native fluid.

4. There is a point of complete mixing of indicator and blood between the sites of injection and sampling.

Although an enormous amount of information comes from the Hemodynamics Lab, the Cardiology Department still uses data collected from other areas of the hospital. That is, significant diagnostic information is supplied by the E.C.G., Echocardiographic Labs, and the Stress Lab. Traditionally, the diagnosis of coronary problems have come from the E.C.G. Lab. However, today this information is augmented from other tests. The E.C.G., however, still plays a prominent role in the initial diagnosis of a problem.

3.3.2 Electrocardiography

The obtaining of the signal of the E.C.G. waveform is the same as that described for the Anesthesiology section of this report. Given the morphology and rate of the resultant waveform, the
Figure 3-6a: Indicator Dilution Curve, test used to determine shunts from one chamber of the heart to another.

Figure 3-6b: Indicator Dilution Curve, test used to determine heart valve incompetence.
cardiologist can often announce the suspicion of a heart defect. In most cases, the diagnosis is made from a twelve lead E.C.G. tracing. This gives the cardiologist twelve different views of the electrical activity of the heart. Since a certain amount of subjectivity goes into the analysis of the E.C.G. to determine what the waveform is indicating, the results cannot be taken as conclusive in themselves. A third set of tests used to give a more accurate picture of the functioning of the heart is the echocardiograph.

3.3.3 Echocardiography

The main principles of the operation of the machine used to obtain the echocardiographs are as follows. When an electric current is induced into a piezoelectric crystal, the crystal vibrates producing sound waves. If a high frequency current is employed, the sound produced is in the realm of ultrasound. By the transmission of these ultrasonic waves through the chest, an image of the tissues and organs traversed is obtained.

When ultrasound waves meet an interface between two tissues of different density, such as fat and muscle, a portion of the waveform is reflected back to the source. The reflections from all the signals employed are used by the machine to create a picture of what has been transversed by the transmitted signal.

When ultrasonography is used for imaging the heart, it is noted that a medium distance penetrating beam is required. If the
source is positioned above different sections of the heart, the dynamic activity of that part can be recorded. By analyzing this tracing, some aspects of the operation of the different sections of the heart can be made. A major consideration which must be made before using ultrasonics for biological imaging is the question of what frequency the sound waves should be transmitted at. This will be seen to be related mainly to the penetrating depth of the beam required, and the resolution of the image desired.[27]

It is known from theory that the absorption coefficient for ultrasound is highly dependent on the sound frequency used. Therefore, the absorption increases greatly with increase in frequency, indicating that frequencies as low as possible should be used. However, there is a lower limit as to the frequency that should be used in this application.[24]

If a sound frequency lower than 0.1 MHz. is used for ultrasound imaging, a divergence of the sound wave of about 90 degrees will occur. Hence, the ultrasound wave will traverse the tissue not as a defined beam but as a waveform spread over a wide angle. Therefore, no specific heart structures can be identified. On the other hand, good definition of the echos dictates the use of a pulse length as short as possible. These specifications limit the useful frequency range for ultrasound to between 1 and 2.5 MHz.[24] The information from the ultrasound imaging is now used to complement the information obtained from the previously
mentioned tests.

3.3.4 Stress test lab.

The third test area for this branch of medicine is the stress test lab. Essentially, the function of this lab is to obtain E.C.G. traces of the heart under stress. This is required as different E.C.G. changes and arrhythmias do not appear unless the heart is under a moderate amount of work. Depending on the purpose of the tests, set routines for the tests done have been devised. The one notable aspect of the tests done is that the patient is presented with a number of increasingly difficult levels of stress. Depending on the patient and the heart ailment, the patient is requested to perform under as many of these levels as possible until an abnormality of the E.C.G. waveform or serious arrhythmias show up. The level of stress performed by the patient and the E.C.G. changes generated by the stress testing is what is now incorporated into the patients' medical data.

3.3.5 Coronary care unit

Also associated with cardiology is the Coronary Care Unit. This area is primarily used to take care of "high risk" cardiac patients. Therefore, in these sections of the hospitals the already described monitoring units for pressure and E.C.G. waveforms, and the life support equipment such as defibrillator, respirators, balloon pumps, and infusion pumps can be found.

Except for the E.C.G., most of the other diagnostic techniques
used here have been developed over the last twenty years. Even today new developments are being made to incorporate the most modern technology available. Truly, Cardiology is a speciality of medicine which relies on technology to help meet its objectives.

Just as Cardiology has seen major developments in the past few decades, another area of the health care industry has also experienced such a growth. Indeed, it has seen its maturation in the hospital to the level of being an important and integral part of the medical industry. This area of course is that of Radiology and the associated areas of Nuclear Medicine and Radiotherapy.

3.4 Diagnostic and Therapeutic Radiology

The branch of medicine which incorporates ionizing, or some other form thereof, radiation as a means of imaging and treating disease has become a very important area of medicine. By definition, this branch is called Radiology, Diagnostic and Therapeutic.[13] The principles involved in the operation of the department are quite complex. Therefore, the department relies on qualified technical personnel, such as the nuclear physicist, for a significant amount of direction and guidance.

There are several different diseases that are treated with the ionizing radiations. These range from hypothyroidism, to the more noted cancerous growth treatment.[5] In addition to the treatment of the disease, the radiant energy is also used for diagnostic purposes. Some of the more noted examples here are the X-Ray and the C/T Scan imaging devices. The internship performed showed
basically three different places in medicine where radiant energies are used. These were the fields of Diagnostic Radiology, Nuclear Medicine, and Radiotherapy.

3.4.1 Radiotherapy

In the case of Radiotherapy, the main objective is to treat a tumor or other cancerous growth through irradiation. This involves bombarding the infected area with either beta particles, or gamma rays. Two of the more common pieces of equipment that may be used to accomplish these tasks are the Cobalt 60 and the Betatron units (Figures 3.7 and 3.8).

The Cobalt Unit operates by emitting collimated gamma rays at the area of interest on the patient. For this reason it is primarily used for the irradiation of deep seated tumors because, the deeper the penetration required to irradiate the tumor, the more energy which is needed by the particles being fired (beta or gamma particles). The source of these radiations is a sample of the element cobalt (60). The apparatus itself is therefore referred to as the Cobalt 60 Unit.[16]

The second of the two devices is a Betatron or Cyclotron. As opposed to the Cobalt unit, this is a beta or high speed electron emitter. In a toroid shaped enclosure (Figure 3.8), the beta particles start out as electrons emitted from a cathode. In the presence of cyclic magnetic fields, the ions are forced to move around a cylinder shaped housing, gaining ever more speed. At some point a negative field is applied at the deflector plate,
Figure 3-7: The Cobalt 60 unit. This device is used for bombarding deep seated tumors with gamma radiations.
directing the ion out of the chamber where it is used to treat the patient. [16] The Betatron can also be used to generate X-Rays. This is simply done by directing the liberated high speed electron towards a piece of material consisting of an element with a high atomic number. [16][26] The aspect of X-ray generation will be covered more in the section on Diagnostic Radiology. Although they are still competent today, the job of the Betatrons as a high speed electron generators is gradually being taken over by Linear Accelerators.

(Diagnostic Radiology)

Before the treatment with the above equipment can be undertaken, some type of diagnosis has to be made to determine its necessity. The department which permits such diagnosis through the imaging of the internal composition of the body, is Diagnostic Radiology. The internship performed showed three techniques used by the department to obtain these pictures. The first of these is through the use of X-rays.

The X-ray machine is the device the general public has had the most exposure to with respect to the Diagnostic Radiology Department. The X-Ray machine is used to image the inside of the body. This device operates by generating X-rays and shooting them at the patient. The instrument used to generate the X-Rays is made of two essential components. These are a high voltage generator connected to a cathode, and a target material made of some high atomic number element. The production of the X-Rays
Figure 3-8a: The active component of the Betatron, the donut. This is the part of the device or component where the electrons are accelerated.

Figure 3-8b: The Betatron. Capable of generating both beta particles and X-Rays.
starts when an electron is emitted from a cathode. In the
presence of a strong electric field, the electron is accelerated
to a high speed. Being directed towards the target, each electron
collides with this high density material and is therefore forced
to give up some of its energy. This sudden loss of energy and
subsequent production of an X-Ray is referred to as
Bremsstrahlung radiation. This radiation is then the X-Ray that
is generated. [16][26]

Because of the variance of radiations that can be emitted in
such a process, many X-ray generators are equipped with
attenuation filters. These are used to try to eliminate any
radiations of energy outside the desired level. Like the target,
these filters is made of a dense material used to absorb the
undesired energies.

The X-Ray radiations are now directed towards the patient or
subject to be imaged. Passing through these bodies, the X-Rays
become attenuated by the different densities they encounter. Some
examples would be the fat and bone found in the body. At the
exiting side of the body for the X-rays, a photographic film
sensitive to X-Ray radiations is placed. It is on this film that
the image is imprinted. If an X-Ray striking the film has
encountered bone along its path, the energy it has left to
imprint the film is comparatively small to those that had
encountered soft tissue. The resulting print is therefore
composed of a number of shades of grey. Such is the output of an
X-Ray Machine. The X-Ray machine is of rather simplistic design, but the resultant information from this apparatus is enormous.

A number of other pieces of equipment are needed to produce quality X-ray images. An example would be what is referred to as a "Grid". This is used to absorb forward scattered radiations during the exposure of the X-ray film. Without such a device, either low energy X-rays have to be used, or else a "fogging" of the resultant image occurs to the extent that some of the finer details of the picture become indistinguishable.

A second form of imaging is essentially obtained with a Photomultiplier (P.M.) tube and a scintillating crystal, as used in an Anger Camera. This piece of equipment operates by having the patient ingest some radioisotope, which is then "taken up" by different organs in the body. The radiation emitted from the isotope, usually gamma rays, causes the scintillation crystal to scintillate, and be detected by the P.M. tube, when the apparatus is located directly above the emitter. If there is a lattice of P.M. tubes, as is the case with the Gamma camera, combining all the information from all the tubes allows for the reconstruction of the organ. This combination and reconstruction is done electronically. The resultant image gives an indication of the amount of up-take of that organ, and hence, a basis for which a diagnosis can be made.

The underlying principle of operation here is that of scintillation. When a gamma ray passes through some compounds,
such as sodium iodine, the gamma ray gives up its energy to that compound. These compounds in turn release this energy, but at a lower energy level. This by definition is scintillation. The lower energy radiations from the crystal, in the visible light region of the energy spectra, are then amplified by a photomultiplier tube. The current output of the P.M. tube is proportional to the gamma radiation interacting in the crystal. Such is one method that gamma radiation is quantized.[26]

A third device which uses the principles of X-rays and the mathematical capabilities of the computer is a computed tomography or C/T scanner. This is used primarily for brain scans, but can also used for stomach and spinal views as well.

Operation wise, the CT scanner has the patient positioned between an X-ray emitter and a series of detectors (such as sodium iodine crystals for example). A highly collimated X-ray beam is emitted from the source such that the beam has a narrow beam width. The pencil beam is detected by a series of detectors, each of which feed their measured gamma ray intensity into a computer where it is stored. Remembering that the intensity of the gamma radiation will be proportional to the density of material it has traversed, each detected radiation will give an indication of the biological material in its path. The next step is an incremental rotation of the source and detectors, and the process is repeated. The process continues until the source and detectors have rotated a full 360 degrees. The computer then uses
all its stored information and some mathematical processing to reconstruct the transaxial slice of the patient.[7]

The CT scan has enjoyed a large amount of acceptance and success over the last ten years. This has been prompted by the fact that it is fast, painless, and the resolution it provides is superior to that of X-rays. It does, however, give the patient a higher "concentrated" dose of radiation than the conventional X-Ray imaging technique, but less of a "whole body" dose.[7]

The final imaging technique to be considered is that of Ultrasonography. Used primarily for obstetrics, as evidenced by observations from the internship, it is also often used to diagnose kidney, liver, and organ blood supply abnormalities. The principle of operation is exactly the same as that described earlier for the Echocardiography machine. In this application however, it must be able to provide a sound wave of deep penetrating ability. The Ultrasonic device is included under the jurisdiction of the Diagnostic Radiology Department, at the University Hospital, because it is an imaging technique using some form of radiation to obtain its objective. It is noted that the form of radiation used here, however, is not the same as for those devices listed above. That is, the Ultrasound machine does not transmit ionizing radiation but rather uses high frequency sound waves.

Besides the above mentioned "high profile" equipment, there are other complex equipment associated with this department. Some
examples of this other equipment are the fluorography machine found in the Hemodynamics lab and the Operating Room, the Image Intensifiers, the Energy Counters, and so on. Taking all the instrumentation associated with this department into consideration, this is an extremely high technology department with many special considerations necessary for its operation.

To contrast this highly complex department, instrumentation wise, one could now analyze a Rehabilitation Department, with its own associated areas of specialization. Such a department was seen to use many different engineering laws and principles in its everyday operation.

3.5 Rehabilitation Medicine

A lighter usage of high technology instrumentation appeared to be present in this department. This is not to say though that the influx of technology into the hospital has not occurred in this department also.

The main aim of this branch of medicine is to provide rehabilitation to disabled patients. This involves attempting to provide electrical and mechanical substitutes or supplements for injured or malfunctioning body parts. To do this, the abilities of the personnel must be extensive. Such is especially true if the amputee is to be provided with a new set of legs which are to function just as well as his/her natural ones. This however is not the only service that staff offer the disabled persons.
In the area of prosthetics and supportive braces, one is obviously concerned with myoelectrics and mechanical prosthetics. Specifically, this requires a working knowledge of electronics and the mechanical properties of stress and strength. However, other areas of knowledge are required. For example, gait analysis, biomechanics, and materials science are but three fields the staff must be acquainted with. This ranges from a knowledge of joint motion and forces, to the strength and wear properties of metals and plastics.

Other areas of this department are involved with trying to help the patient cope with their functional losses. Specifically, this could include the recent amputee, the patient with a skull or spinal injury, or those whose mobilities are restricted due to arthritis. The branch of Rehabilitation Medicine concerned with these aspects are the Physiotherapy (P.T.) and Occupational Therapy (O.T.) departments.

Although substitutes can be given for lost limbs, or devices designed to aid worn out or malfunctioning body components, the patient must also be given therapy to help him/her operate with these substitutes. Alternatively, the crippled and aged must be taught how to maximize their existing capabilities. This, as mentioned, is included in the functions of the P.T. and O.T. departments. In both cases, the objective is to provide the patient with the optimum living environment for the specific disability, or maximize the patients' existing abilities.
By definition, the Physical Therapy department attempts to develop a handicapped patient's abilities through the use of physical therapies.[13] These would include heat, biofeedback, and physical muscle manipulation. The Occupational Therapy department, alternatively, uses occupational activities to enhance and develop the patient's abilities.[13] For instance, this department uses such activities as cooking and sewing to develop the hand manipulations for those with arthritis.

These two areas of the overall department can be seen to require different modalities and equipment to do their work. In most cases, the success of the treatment relies on the diagnostic and therapeutic capabilities of the staff. There is however, as with the other departments of the hospital interned at, a large number of scientific and engineering principles and apparatus now being used within this particular department.

In some cases, ingenuity on the part of the P.T. and O.T. staffs are also prerequisites. This is required because of the objective of providing the patient with a means of existing with the disability and still function despite it. In other cases, industry and society have attempted to help. Some observed examples are the automatic page turners, systems to help the crippled drive again, braces, as well as subsidized supply centers from which the patient can obtain the necessary aids for their disability. Further, more technically advanced apparatus are present in the Physiotherapy Department. Here, modalities
have been developed for deep heating effects, biofeedback, magnetic and ultrasonic stimulation, as well as ultraviolet therapies. Some of these therapies are facilitated through the use of micro-waves, ultrasonic and ultraviolet sources, biofeedback monitors, and magnetic field generators.

Many of these above modalities though have experienced difficulties and/or shortfalls in their implementation and expected results. In fact, it was observed that it is the ability of the personnel here in applying the physical modalities that provide the real success.

The above statement is felt to be applicable to the operation of the entire Rehabilitation Department as a whole. That is, it depends on the capabilities of its staff being able to recognize the problems, suggest the modality to be used (often a physical one) and prescribing what ways the patient may be aided in coping with their disabilities. It is with the third that the practice of engineering may play a part. Usually it merely involves a person being able to recognize the application of some simple device to satisfy a basic principle.

Just as one altered his thinking, changing from considering Radiology and its associated fields, to Rehabilitation Medicine, one can now make a change back to a high usage area of medical instrumentation. The extensive use of technology by the Pathology department can be compared to the extensive use the Radiology departments make of technology.
3.6 Pathology

Pathology can be defined as that branch of medicine related to the study and diagnosis of the essential nature of the disease, especially of the changes in body tissues and organs which cause or are caused by disease. [13] To obtain this goal, many different sciences and branches of medicine are employed. In fact, this area of medicine is one of the more active departments with respect to medical research. Three areas of the department attended by the students during the internship were Chemical Pathology, Hematology, and Histology. The tests done in each of these three different sub-branches of medicine include cell counting, serum analysis, protein determinations, grouping of leucocytes, as well as the analysis of tissue cells.

The tests that the department of Pathology performs have evolved over many years of intense research. Accompanying these developments has been the move within the Pathology Department to automate the instrumentation used there. One of the main reasons for the push for automation in the laboratories is to reduce variations due to differential technician capabilities. The second major cause for the developements of automation is to accomodate the increased work loads imposed on Pathology departments in recent years.[24] Despite these two factors though, in the Pathology Laboratories the amount of manual work, as opposed to the automated techniques using instrumentation to be described below, has actually increased in recent years. One of the leaders in the Pathology department in the use of high
technology instrumentation for the purposes of automation was observed to be the sub-department of Chemical Pathology.

3.6.1 Chemical Pathology

One of the supportive sciences employed by the department of Pathology is analytical chemistry. This is due to the fact that Pathology must concern itself with the analyzing of human cells, serums, and tissue. As experienced by the internship performed, this area of Pathology is one that the Clinical Engineer might be more involved with. This observation was based on the fact that a large amount of instrumentation was seen to be used here, moreso than the other branches of the department.

It is recognized that in the Chemical Pathology Lab major strides have been made in the attempts to automate.[24] These include the use of auto-analyzers, dedicated computers, Automated Chromatography units and Electrophoresis. Of these devices, the three which were seen to be most often used were the auto-analyzer, the chromatography, and the spectrophotometry units.

The auto-analyzer, of which there are several variations, has acquired the reputation as the "work horse" of the lab.[24] As there are several different manufacturers, there exist many different procedures for doing this test. An example of such an analyzer is the SMA 12/60(TRADEXAME). The test procedure of this particular instrument then is as follows:[24]
1. Sampling

2. Treatment (to bring out the desired substances from interfering substances by precipitation, extraction, dialysis, etc.).

3. Reaction with a reagent.

4. Period of waiting (for equilibrium in the reaction, incubation, etc.).

5. Measurement of the chemical state of the test substances.

6. Data logging, calculation, data storage, reporting, etc.

Mentioned above was the fact that there are a number of different variations of this device. The schematic of Figure 3.9 illustrates these variations in the different ways the test procedure can be carried out. Some of the specifics the auto-analyzer is used to test for are:[24]

1. albumin
2. calcium
3. glucose
4. inorganic phosphate

One or several of these tests may be required for all serum samples. Therefore, it can be understood why the Multichannel Auto-analyzer is so widely used.

The auto-analyzer is used to determine proportions of known constituents in the sample, but it is often desired to know what unsuspected components also are also present. This is almost universally done through the use of chromatography, and/or
Figure 3-9a: The test procedure for the multi-channel auto-analyzer.

Figure 3-9b: The different types of analyzers available. This facilitates single or multiple samples at the same time, with single or multiple tests being done.
spectrophotometry. For chromatography, the theory of operation is surprisingly simple. The operation of the chromatography unit depends on detecting the phase changes of the substance determines the different constituents of the test sample. For example, in one form of chromatography unit, the detecting of the elements is relative to the changes that occur when the sample goes from a liquid to a gas phase.[24]

The operation of a spectrophotometer can be quite different from the principles already mentioned. It is noted though that some auto-analyzers do use spectrophotometry units in their design. The principle of operation of one type of spectrophotometer unit, the Flame Spectrophotometer, is to measure the light absorbed by a sample. Here, the material is sprayed into a flame and caused to become a vapor. Through this vapor is directed a light beam of a characteristic wavelength of the element to be analyzed. The beam then falls on a monochromator and then to a P.M. tube. The absorbance of light by the flame is proportional to the concentrations of the element found in the sample.[24] It is noted that this technique is more widely used for the analysis of minerals in the body.[24]

Another newer form of spectrophotometry is Atomic Absorption Spectrophotometry. This method was developed principally to determine low concentrations of metallic elements in biologic fluids and tissues. The principle of operation is similar to that of emission flame photometry except that the measurement is of
light absorbed rather than emitted; the number of atoms taking place in the absorption is greater than that of emission, since, in the latter case, only a small number of atoms is sufficiently excited to become luminous.[24] In either case though, the standard spectrophotometer is noted to work on a liquid sample.

Except for the analyzing and categorizing of proteins in the blood, the three above mentioned instruments would adequately perform the blood analysis required. To determine the proteins, however, the technique observed to be used is that of electrophoresis. The theory here is to quantify and qualify the proteins in a sample from their migrations when acting in an electric field. This modality has been found to give excellent definition of the proteins present in a sample of blood.

As is the case with many other of the areas of medicine, the Chemical Pathology Department also uses of a large amount of other, "supportive", equipment. For instance, no Chemical lab could operate without a centrifuge. In fact, most labs are equipped with several. Other examples of supportive equipment located here are fume hoods, sterilizers, and, more recently, the computer.

The main observed use the Pathologist has made of the computer is as a data bank, or an area for doing statistical analysis on data. Industry has facilitated this use by incorporating computer technology into the design of their equipment. This was seen for the "M Analyzer" multi-channel analyzer, and other high
profile equipment in the department. In a Chemical Lab in particular, there is a large amount of data that has to be recorded and saved. With the advancements in the computer industry, this area of medicine has been afforded a cheap, compact, easily accessible medium for mass data storage. Together with the automation of the Pathology Lab equipment, modern installations are also designing their labs around, and purchasing equipment which is readily able to interface with a computer. Current indications are that all future Pathology Laboratories will have instruments with their data outputs connected directly to a computer. Now, any calculations can be done, and a standardized format for the data printed out.

The Chemical lab is not the only area of Pathology that makes use of a computer. Certain portions of Hematology are also having their equipment outputs tied to a computer, usually the same one as mentioned above. One advantageous side effect of this centralized data storage system is an improved communication between the two departments, as well as with the rest of the hospital.

3.6.2 Hematology

The main function of the Hematology Laboratory is the analysis of blood cellular components. This includes the quantitative determinations of the different constituents of the blood. The equipment used in Hematology for these determinations are the cell counters such as the Hemalog 8/90 (Tradename of Technicon)
and Coulter Counters (Tradename), for such blood component analysis as the determination of hemoglobin and cell numbers; and the Hemalog D/90 (Tradename of Technicon) analyzers (for leucocyte determinations).[29] These two devices have been modernized, as was the case in the Chemical Lab, due to the attempt to automate the laboratory as a whole. Again, as was seen in the Chemical lab, the information discharged from these two devices is rather large. Therefore, in the lab visited, an interaction with a computer data base system similar to the one mentioned above was observed.

Of the newer instrumentation used here, one of the older pieces of equipment used in the Hematology Laboratory is the Coulter Counter. The basic information about the blood determined by this device is the same as the Hemalog 8 cell counter mentioned above. The techniques used by each instrument to obtain the data however are quite different. First, the operation of the Coulter Counter will be considered.

With reference to Figure 3.10, the cell counting process of the Coulter Counter is done basically by detecting current, or impedance, fluctuations between two electrodes. These fluctuations are caused when the cell of interest (R.B.C., W.B.C., or Platelets) enter the hole in the tube. This increases the impedance between the electrodes, and hence a change in the current.[24] Although simple, this instrument has remained essentially unchanged since its initial design.
The active component of the counter. The actual cell determinations occur here.

The blood sample.

Figure 3-10a: The Coulter Counter. Used in the Hematology Lab. for the analysis of blood.

Figure 3-10b: The active component of the counter showing the principles of operation.
To contrast the operation of a Coulter Counter, some of the characteristics of the Hemalog 8 will be discussed. The information from this device is basically the same as that derived from the Coulter Counter. These are: White cell count, Red cell Count, Platelet count, Mean Cell Volume, Hematocrit and hemoglobin. As mentioned, it is the means by which the parameters of the blood are determined that differentiate the two instruments.

The blood sample is first split into smaller samples to be used to determine the white, red and platelet cell counts, hemoglobin, and hematocrit tests. The hematocrit is determined by actually centrifuging the sample. The hemoglobin is obtained by staining the sample and subjecting it to testing with a colorimeter. For the cell counting, after each of the remaining three split samples has been properly treated with reagents, the counting process is as follows. Particles are counted using the dark field principle. Light passes through a condensing lens uniformly illuminating the primary aperture. A projection lens detects light passing through this aperture and forms a reduced image of the aperture in the center of the flow cell. This results in a small brightly illuminated view volume, sharply defined by the reduced aperture image and the sides of the flow passage in the flow cell. The light then emerges from the flow cell, and is blocked by a dark field disc which prevents any direct light from striking the photomultiplier tube.[29]
If a clear fluid passes through the flow cell, the light rays are blocked by the dark field disc as described. However, if particles, such as cell, are dispersed in the fluid stream, they are illuminated as they pass through the view volume. When illuminated they become secondary sources of illumination, scattering light in the forward direction, toward the objective lens. This collects and focuses the light through a small aperture in front of the the photomultiplier tube. Thus, as each particle passes through the view volume, an electrical pulse is generated.[29]

An inherent problem with the Coulter Counter is the plugging of the entrance hole into the tube. Also, the Coulter Counter determines the hematocrit based on the cell volume while the Hemalog 8 actually centrifuges the blood. This could result in an error in the hematocrit specified by the Coulter Counter due to a compounding error. However, despite these faults, the Coulter Counter still has an advantage over the newer Hemalog 8 cell counter. This advantage is that the Coulter Counter can analyze a smaller blood sample. This however is provided that the sample is first prediluted.

Once again, this section of the Pathology has supportive equipment. For example, an automated device for putting the W.B.C. samples on microscope slides is incorporated in the operation of the Hemalog D (Tradename). Also used are light microscopes (which are used extensively here), centrifuges, and hand counters. Indeed, the use of light microscope by the
Hematology lab rivals that of any other piece of equipment used there. This is also an important instrument to another area of the Pathology Department.

3.6.3 Histology

Equipment such as microscopes (electron and light) and centrifuges, although supportive in other areas of Pathology, are mainstays of the Histology Lab. In this lab there did not appear to be the widespread usage of technologically advanced instrumentation. However, it is realized that advanced scientific processes for the analysis of tissue cells are used by, and developed in, this department. Aiding these developments, being used quite extensively in the day-to-day operations of the department, are the microscopes (electron and light). Other essential instruments to the Histology Lab are microtomes, automatic tissue processors, as well as instruments associated with the dyeing of the tissues. It was seen that the bulk of labor done in the Histology lab was performed manually by the technicians.

In a large hospital the department of Pathology can be viewed as being comprised of several sub-specialties. The one basic relationship the departments share is that they are concerned with the analysis of some of the human body's components. This includes both the body fluids as well as its tissues. Such an association, with several areas of medicine under the jurisdiction of one overall department, was seen to prevail
throughout the hospital.

If the last statement preceding paragraph were applicable to the other areas of the hospital, then Cardiovascular Surgery might be classified under the jurisdiction of a division of Cardiovascular Sciences. The Cardiovascular Surgeon is obviously concerned with the heart and its circulatory system. This factor however also involves the Cardiovascular Surgeon in many other fields of endeavor.

Consider first that the Cardiovascular Surgeon operates as a member of a surgery unit and is therefore concerned with surgical procedures. Additionally, since the Cardiovascular Surgery Department is often involved with the implantation of foreign materials such as pacemakers and heart valves, it is also keenly interested in material science. Therefore, when considering the Cardio-Vascular Surgery Department, it is best to do so as an entity unto itself.

3.7 Cardio-Vascular Surgery

Working as a member of a Cardio-Vascular team, one is acutely aware of the need for a sterile operating environment. With cardio-vascular surgery, this point must be carried to the extreme as the surgeon is handling, replacing, or augmenting different parts of the cardio-vascular system. In particular, he is physically handling the heart. This includes valve replacements, diastolic augmentation devices (Intra-aortic Balloon Pump), pacemakers, and so on. Therefore, this surgeon
has to be aware of the different types of problems that can be caused by such activity. Problems can arise due to the biological system responding to the implanted devices, in the attempt to eliminate these foreign materials. The response of the body in this way may result in infection. Therefore, modern technology have had to try to at least lessen, if not overcome, these infections.

Cardiovascular Surgery like the field of Cardiology owes a lot to technology. This is true since it has only been since 1952 that heart valve implants have been undertaken.[24] At the time, an immediate realization was that the environment that any mechanical valve was subjected to previously was totally different to that of the inside of the human body.[24]

Due to this alien environment, some of the considerations that have to be made before an implantation can be undertaken are:[31]

1. biocompatibility
2. wear properties of the implant material
3. strength of material to cyclic loads
4. anti-thrombosis properties
5. physical size
6. physical design of the valves

These properties, although specifically mentioned for the heart valves, must be common for all materials implanted in proximity to the cardio-vascular system.
The advancements of technology have been such that the major considerations today have had to be with respect to the materials used, its resistance to wear, and the flow properties of the blood through the valve. This last aspect is of significant consequence as, if the effects of a turbulent flow in the vicinity of the valve are not taken into consideration, the blood trapped here will embolize creating a potentially lethal condition.

The above problems are of lesser significance to the pacemaker. This is true since the only part of the pacemaker in contact with the blood system are the leads. The question of biocompatibility of the materials used in pacemakers are still of primary importance since the pacemaker is in physical contact with the body tissues.

The implantation of devices such as heart valves and pacemakers, and the subsequent results of these, have accentuated the need for knowledge in both materials science and mechanical design by this department. Additionally, other areas of science have had to develop in order to permit the implanting of these components. First though, the doctor must get to the heart, or where-ever the site of the surgery is to be.

In order for the surgeon to work on heart valves, incisions through either the heart wall or the aorta are required. Unless proper precautions are taken, this can result in the patients' blood draining out of the systemic blood system. The answer to
this problem is the incorporation of a bypass.

In an operation requiring a bypass of the heart, the general procedure is to shunt the heart completely. That is, divert the flow of blood from where the vena cava enters the heart to the ascending aorta, thus bypassing the heart completely. As a result there is then no flow through the heart, hence no motion. This provides the surgeon with a more stable operating area. Such a route for the blood however, completely bypasses the pulmonary circulation. Therefore, the bypass must also provide some means of re-oxygenating the blood.

The piece of equipment used for the heart bypass is referred to as the Heart-Lung machine. This apparatus takes the blood shunted from the vena-cava, passes it through an oxygenator, and then pumps the blood into the ascending aorta.

There are presently two main types of Oxygenators available.[24] These are differentiable by the way they oxygenate the blood. The first method uses a bubble oxygenator. In this method, reoxygenation is achieved by bubbling the oxygen through the blood. The second technique operates with a membrane, where the oxygen is diffused across a semipermeable membrane into the blood. Both these methods have been found to be adequate in loading oxygen onto the blood for a limited period of time of three hours.[24][31]

Since Cardiovascular surgery is associated with the diseases of
the heart, another piece of equipment is often required by the department. This is the Intra-Aortic Balloon Pump. Used primarily to augment the diastolic pressure, this device requires a balloon be located in the Descending Aorta. By triggering off the E.C.G., the balloon inflates during diastole, immediately after aortic valve closure, to raise the pressure during this segment of the cardiac cycle. This has the effect of increasing the pressure so that the perfusion of blood in the coronary arteries is also increased. Deflation of the balloon is effected just as ventricle contraction begins, causing a lowering of aortic pressure and hence a lessening of pressure work required of the ventricle.[24]

There are several newer pieces of equipment and procedures now available to the Cardiovascular Surgeon to aid him meet his goals. These include the electro-surgery (diathermy units), monitoring devices (pressure temperature and heart rhythm), sterile procedures, as well as new surgical techniques pertaining to the physical aspects of the operation. From the above paragraphs, it is apparent that the Cardiovascular team has to have a multidisciplinary staff.

Several areas of the hospital have a similar need for a large knowledge base in order to ensure their efficient operation. One department requiring such expertise is the Engineering and Maintenance Department.
3.8 Engineering and maintenance

At the base of operations for many departments in any health center is the Engineering and Maintenance Department. Not only is it the responsibility of these people to ensure the smooth and reliable operation of hospital equipment, but in many cases they influence administrative actions in other departments.

As its name implies, the duty of the Engineering and Maintenance Department in a hospital is to maintain some aspect of hospital operation, or oversee the general engineering considerations in such an institution. This often involves dealing with the hospitals' environmental operating characteristics. As indicated by the internship, the areas of primary concern deal with the demands for heating, cooling, plumbing, and electrical supplies for all the departments within the hospital.

Taking an even closer look at the responsibilities of the personnel in this department, they are primarily required to look after the repairs and general maintenance of many of the equipment aspects of the Hospital. For example, one of the main areas of concentration for this department is in dealing with the heating, ventilation and air conditioning (H.V.A.C.) aspects of the hospital. The method of meeting such demands is well understood, and not technically intensive. This is not to say that the equipment involved with is insignificant in terms of cost or size though.
With the different hospital departments usually requiring different environmental operating conditions, it is the task of this departments' personnel to attempt to supply these individual requests, economically. It quickly becomes apparent that the brunt of the Engineering and Maintenance Departments' efforts go into the controlling of the comfort conditions in the hospital. Although this aspect of the department does place a heavy demand on the total staff time, the concerns for the H.V.A.C. are not the only areas of the hospital's operation that the department must concern itself with.

Another responsibility which is integrated with the previously mentioned function is the maintenance of the standby power plant. The department must guarantee an uninterrupted supply of electricity to the entire hospital. With the possibility of city wide power outages effecting the power supplied to the hospital, the department must ensure that there is an operational backup generator available. This is a major concern of the department, but is still not the extent of all its operations.

Assigned to the duties of the Engineering and Maintenance Department are those concerning the services needed to keep the appearance, and security of the institution at a presentable level. This includes the areas of: Housekeeping (keeping the building clean and sanitary on the inside), Grounds (involved in snow removal in the winter and grounds maintenance in the summer), Security (for the inside of the building), and Carpentry
A final and very important area observed to be under the jurisdiction of this large department is Electricity and Electronics. The first of these is concerned with the more industrial aspect of electricity in the Hospital. This involves the repair of communications devices, and the stringing and subsequent connecting of electrical cables. The second branch of this department is involved with the maintenance of medical instrumentation. Ideally, it is the function of this branch of Engineering and Maintenance to repair medical equipment and ensure continuous and reliable operation of that equipment. During the internship, this was observed to be a very important and crucial department in the hospital. This point will be elaborated upon later in the report.

The final objective of the Engineering and Maintenance Department is to minimize their equipment failures. During the internship the initiation of a Preventative Maintenance program (P.M.) in one of the centers interned at was monitored by the students. Such a program is a common way the Engineering and Maintenance Departments try to prevent major problems with respect to the operation of the hospital as a whole. Also, it is a means by which the hospital copes with problems that are related to the technological aspects of the equipment and operating routines in the different departments. As such, the P.M. program requires a set schedule of performing operational
checks on all the above listed areas of the departments jurisdiction. This aspect of the department is new and its need only recently been recognized. Therefore, as discovered during the internship, problems can even exist in a program designed to identify difficulties.

This concludes the discussion pertaining to the different principles of operation and engineering concepts that were seen to be used in the Health Care System. It has been shown that several different principles and equipments are incorporated in the operation of any one department in the hospital, let alone the whole complex put together. These technical aspects of the operations of the hospital are seen to be points where problems can arise.

With so many different and varying processes being applied by the Health care system, a highly specialized and technically minded department may be required by the hospital in the near future. The main reason for this is that with the influx of technology into medicine problems arise that are beyond the capabilities of the present staff. Two sources may be cited as to why these problems may develop.

First, there exists the possibility for hospital personnel to be given improper initial training on their instruments operation. Secondly, the staff may develop, for one reason or another, an incomprehension of the manufacturers' intended uses of the equipment. For these two reasons it is felt that the
staffs of the different departments should not be expected to unduly concern themselves with all the technical aspects of the equipment they use. It is suggested then that, in conjunction with the current hospital personnel, a Clinical Engineering department be assigned the responsibility of overall equipment management.

During the internship a number of observed operating problems, irregularities or misunderstandings with respect to the equipment used were observed. These are the main reasons why the suggestion that a technically orientated department be established in the hospital is made by this report.

The function of this suggested new department would be, in co-operation with the existing departments in the hospital, to assist in attending to the equipment concerns of that hospital. Examples from the internship which indicate the hypothesized need for this department were noted. Also, for the problems observed during the internship and which are used to support the above argument for the creation of a Biomedical Engineering Department in the hospital, in this report are given reasons for these problems existence and possible solutions suggested. This is the material which the report will now consider.
4. ENGINEERING EXPERIENCES IN THE CLINICAL ENVIRONMENT

In the preceding chapter, a number of very complex pieces of medical instrumentation were introduced. The fact that there is such a large use of such instrumentation in the hospital could indicate the need for Clinical Engineers in the hospital. This would be to act as the personnel whose responsibility would be to oversee this aspect of the hospitals' operation. Specifically, it is proposed that the creation of such an entity in the hospital would be to enforce the seven responsibilities of a Clinical Engineer as listed in Chapter 2 and pertaining to the equipment listed in Chapter 3.

The majority of the material contained in this chapter was obtained from an eight month internship in a 540 bed hospital. Also, however, is material gathered while visiting three other Health Care Centers in the Regina region of this province (see Appendix III). It is felt that the internship provided a fairly representative example of some of the problem areas that can exist in comparable sized hospitals.

Some of the department heads in the hospitals interned at recognized that problems existed and took the opportunity afforded by this internship to try and rectify them. However, many of the problems were totally unnoticed by some of the staff. This occurred even though the cost of the equipment and associated operational costs were high. This is precisely what the Clinical Engineer is proposed to help try to avoid.
To indicate the observed need for Clinical Engineers, and report on the ways the students applied their engineering abilities during the internship, this paper will now outline some of the problems hospital instrumentation can pose in medium size health care centers. In essence, this will include the projects and questions encountered in the different hospital departments which the students visited.

4.1 Staff education

One of the major proposed roles of the Clinical Engineer will be to assist in the teaching of the hospital staff about the engineering principles and equipment used there. This instruction would not be limited only to the high technology equipment. Additionally, the teaching aspect will not limited to one particular type of hospital employee. Indeed, personnel ranging from administrators to doctors and nurses to technicians will eventually require assistance coping with the complex matters of medical instrumentation that is to be used in the hospital.

4.1.1 Instrumentation users

The personnel that have to operate the equipment (the nurses, doctors and technologists) are the persons who should receive the highest allotment of the Clinical Engineers' teaching time. Several cases can be cited where this need was observed.

One such incidence where constant teaching is required (for the nurses at least), concerns the placement of chest electrodes on
the patients.[22] This area concerns the Clinical Engineer due to
the fact that improper placement of electrodes into an area where
there is a lot of movement can result in major noise artifacts
appearing in the signal. Since it will be the Clinical Engineers
responsibility to reduce the noise component in the desired
signal as much as possible, this source of noise is one that he
must take into consideration.

Such a problem with electrodes was observed many times in the
Operating Rooms (O.R.) and other monitoring areas. During the
monitoring with such improper placements, large noise artifacts
were observed. When this happened, it was often deemed to be the
fault of the electrodes. To avoid this problem the suggested
areas of the chest where relatively small movements occur, and
where it is suggested the electrodes should be placed, are shown
in Figure 4.1.

Associated with the problem of electrode placement is the
proper preparation of the electrode application site. For this
aspect it is desirable to have the area as clean as possible.
Again, this was an area where the staff (the nurses in
particular) needed constant review.[22]

A second case which emphasizes the need for more educational
activity in the hospital was seen to occur in the Operating Room
(O.R.). The O.R. is noted to be an area where there is a great
risk of an accidental microshock: a low level electric current
applied through a low impedance pathway to the heart muscle.[8]
Figure 4-1: Suggested areas of E.C.G. lead placement
The result of such a low resistance shock is that the patient may go into ventricular fibrillation. What makes this more insidious is the possible sources of these shocks. In this case the specific problem arose from leakage current levels in the O.R..

In all the above critical care areas leakage current monitors exist. These devices, used with ungrounded systems, measure the equivalent impedance (capacitive and/or resistive) from either side of the supply line to ground.[6] They in essence measure the leakage current from the supply line to ground in these "special monitoring" areas, and indicate if it exceeds a safe value. The leakage current suggested as the standard is in the low microamp range, being approximately 10 microamps in areas where there are direct paths to patients' hearts (for example, in the C.C.U. where patients have catheter electrodes directly in contact with the surface of the heart).[8]

During an open heart surgery one such leakage current monitor sounded its alarm. The actions taken by the Anesthetist, after checking the patients' leads catheters and electrodes, included walking around the O.R. theater pulling equipment plugs in the attempt to locate the fault. The apparatus causing the problem was located and disconnected within a couple of minutes. A point may be made though that precious time may have been used to discover the source of the fault.

Through the Clinical Engineer, it is suggested that the anesthetist may be able to derive a more systematic method of
determining such sources for leakage current alarms. It is felt that through a statistical analysis, the most probable pieces of equipment where faults may occur can be listed. To do a thorough statistical analysis though would require a knowledge of the operating principles of all the equipment used in the O.R. Hence the reason for using the Clinical Engineer who is responsible for knowing such information. A "spin off" of this proposed statistical study would be that the Maintenance Personnel could also know the instruments that are most probable to cause problems. Therefore, more attention can be given these pieces of instrumentation by the Maintenance Personnel.

Further evidence supporting the need for constant teaching of the staff was observed in the Coronary Care Unit. The problem here involved an arrhythmia detector. This device was seen to operate by comparing each heart waveform to a set of heart waveforms (template) reviewed and decided to be a norm for the individual patients. The particular problem occurred due to the staff becoming too accustomed to the device detecting false arrhythmias so that when one finally occurred, they considered it also false. Upon closer inspection the fault indicated was that the patients' pacemaker did not capture. This meant that the pacemaker sent out a pulse that did not cause the heart to contract. Hence, it took two pulses from the pacemaker to force the heart to contract.

Such a source of trouble with respect to arrhythmia detectors
is important to the Clinical Engineer as it may be the cause of repeated problem reports for the system by the C.C.U. staff. Possibly then, a review of each staff member's performance with the system should be done. Although this would not be the function of the Clinical Engineer, his involvement in such evaluations may be necessary as he is the one who is usually presented with the proposed problems of the system by the staff. To play such a role, the Clinical Engineer will have to have a good medical knowledge of the functions performed by the system. This is so as to be able to identify legitimate problem reports.

A final use for the teaching abilities of the Clinical Engineer may be required, it is hypothesized, in the event that insufficient training is provided by manufacturers for the instrumentation used in the hospital. Since the Engineer should have more overall experience with complex instrumentation, that person may be able to provide aid to a department faced with the problem of not being supplied sufficient education on the operation of newly purchased devices. The Engineer, in cooperation with the head of the department purchasing instrumentation could definitely ensure the purchase of adequate equipment by the department. Thus, it may be of benefit to have the Clinical Engineer present when planning to purchase instrumentation. It can be easily hypothesized though how events, without the influence of personnel familiar with complex instrumentation, may lead to the purchase of inadequate equipment and/or, subsequent to purchase, insufficient training for the
personnel to be using the device.

In terms of economics, such a practice is very poor. Such is due to the possibility of the operator spending months experimenting with the device to learn all its operating modes. Also, there exists the probability that all the machines capabilities may never be discovered. Finally, there is a chance that due to improper operator training the device may accidently be damaged. This kind of practice can lead to undesirable side effects.

A primary side effect of insufficient training, from observation, is that operators develop skepticism towards the instruments they are working with. The net result is that they are constantly questioning the results, not because they should be questioned, but rather because of the operators personal uncertainties. These self doubts arise from those persons who are not entirely certain that they have followed the operating procedures correctly.

Based on the above hypothesis it may be the case that the hospital administration are the ones that derive the most benefit from the use of a Clinical Engineer. This concerns the spending of large sums of money on instruments while also ensuring that the equipment is supported with properly trained personnel. Other instances can be given which indicate that this is not the only area where administration can make use of a proper Clinical Engineering Department.
4.1.2 Consultation for the clinical environment

Since the Clinical Engineer must expect to act as a consultant, he must also be prepared to encounter personnel requesting equipment of which they are not certain exist, or are unable to properly describe. The possibility of this event occurring dictates that the Clinical Engineer be well versed in medical terminology. Such a case did occur when an administrator from a small hospital requested information about an electronic Intra-Venous (I.V.) pole. This inquiry was made of the Electronics Department of the larger regional hospital.

Due to the vagueness of the device description, it was suggested that the instrument not be bought. Although the actual device may be needed by the hospital in question, this was felt to be the best suggestion possible. This is due to it being better that no device be bought if there is the possibility of buying the improper piece of equipment because of a poor device description. The most appropriate course of action may have been for the Electronics personnel to deal directly with the head of the department for which the instrument was to be purchased. This would allow for the consultant to develop a clearer concept of what was desired. It would also allow for the true need of the device to be evaluated for both its technical necessity as well as its medical necessity as determined by the head of the department.

Perhaps what that person in the above example wanted was not an
electronic an I.V. pole, but rather an infusion pump. This in all probability was what was required. However, as the administrator was not sure of the device desired, and since the department head wanting the instrument was not consulted, at the time in the internship that this incident occurred the suggestion was to not purchase the device.

The next example involves a smaller hospital which had been donated money for a specific piece of equipment, this again being an infusion pump. The hospital administrator seeking advice about the pump was advised against getting it, to the extent of refusing donated money. The reason for the suggestion was that the small hospital did not, and would not be using infusion pumps in the foreseeable future. Such an evaluation on the part of the Electronics Department acting as consultant was felt to be valid based on the association between the two Health Care facilities through a "shared services program" provided by the larger center. Therefore the Electronics Personnel in the larger hospital were aware of the situation and many of the instrumentation needs of the smaller hospital. The administrator accepted the advice and did not get the pump.

This example shows where a technically minded person saved the hospital from troubles by advising it not to get the infusion pump. The problems that may have arisen from the purchase of the device are: First of all an unused piece of equipment would simply be lying around. Secondly, if the equipment was to be
used, the hospital would have to train its staff on its proper use.

Many more cases can be cited which reveal the need for a Clinical Engineer in the hospital for the purpose of teaching. Additionally, the Engineer is required for consultation purposes in the clinical environment, and specifically to aid the hospitals administrators. This is not the only place the Clinical Engineer should expect to be asked for advice. Indeed, the area of medical research and device evaluation is an area where consultation is always needed. Such a statement is particularly true in a teaching hospital. This was clearly evident in different of the aspects the students were asked to investigate during the internship.

4.2 Research consultation and device evaluation

Of growing importance to the doctor is the consultation and advice he can obtain from a Clinical Engineer. This is true in teaching hospitals which are by definition, involved in medical research, as well as medical instrumentation evaluations. During the Clinical Engineering internship a number of such requests from doctors were presented to the students.

Several different projects and investigations were undertaken by the students. All were related to some research or evaluation aspect in which the different department heads were involved. In the following paragraphs, a short summary of each problem will be given, as well as the suggested solutions.
4.2.1 Heart valves

One of the recent advancements made by medical science is the capability to replace incompetent heart valves. This advancement has not been without its own share of problems. Some of the difficulties encountered in the replacing of heart valves have been due to engineering design problems. Indeed, several problems and failures related to these design faults still plague the heart valves used today. These recurring failures cause a great deal of concern to the Surgeon and the Cardiologist. It is also the surgeon who is constantly questioning modern science about new materials and techniques, and asking the manufacturers for improved designs to permit a better success rate.

Although no Clinical Engineer would be able to change the design of prosthetic heart valves on his own, he may be asked for consultation from a surgeon, whose influence may cause the change in design of heart valves. The Clinical Engineering students then, for different reasons, were asked to evaluate present day valves and summarize why they fail. Following this it was desired that the findings be discussed with the Cardio-Vascular surgeon, and their suggestions for a possible alternative design be given. Such an exercise was proposed so that the students could obtain an insight into the considerations that must be made in the field of Cardiovascular Surgery. It also provided the surgeon with an opportunity to question the engineering principles associated with this aspect of medicine. The investigation itself involved reviewing the short-comings of valves that are no longer used,
and looking at the recognized problems with today's valves. (Examples of these valves are shown in Figure 4.2).

The major factors observed to influence the operation and longevity of the heart valves are as follows:[25]

1. Biocompatibility - The measure or the body's reaction to the implant material.

2. Thrombogenicity - The tendency for thrombus to build up on the implant material.


4. Fluid dynamics of the blood passing through the valve.

At least some of these considerations were deemed to be prerequisites in the design of any prosthetic heart valve used today. For the xenograft valves (valves using porcine leaflets) it is the strength factor (affecting the long term competence of the valve) that is of most importance. Since the strengthening of these valves is mostly through chemical treatment of the leaflets, the students were not experienced enough to provide beneficial input. As a result it was the non-xenograft type of valves that they were more concerned with. For the non-xenograft type valves the fourth factor is the most important. It is also one of the main reasons why the older models of heart valves are no longer used (i.e. caged ball).[2]

Specifically, these valves promote too much of an increase in the turbulent flow of the blood about the valve. Hence, some of the blood may become stagnant, thrombose, and embolize. An
Figure 4-2: Types of prosthetic heart valves in common use. Table above gives summary of different designs that have been employed. Picture above shows two of the more common designs still implanted. The Star-Edwards aortic valve, left, and the Bjork-Shiley tilting disk.
increase in the turbulent flow is promoted in the mechanical valves because of the center of the orifice is obstructed.[15] Different designs today attempt to prevent the possibility of these stagnant areas developing around the valves. However, some excised mechanical valves were observed to have thrombus on them. It is felt that the major cause of these problems is the obstruction at the center of the orifice.

Some of the valves used today are made of a substance called "Pyrolyte". This substance has really developed into a good material for heart valve prosthetics. First, because of its carbon components, it is almost physiologically inert. To a large extent "pyrolyte" also overcomes the biocompatibility problem. Additionally, the material has a high polished finish common among ceramic materials. Because it is so highly polished and inert, many of the thrombus problems are eliminated. Finally, it also meets the strength considerations required in a heart prosthesis.[2][4] It is quite easy to say that for this material, the field of cardiovascular medicine owes much to the advancements made in materials science.

Based on the above facts, the suggestion given to the surgeon was that: A better design for heart valves would eliminate the center of the orifice obstruction. However, this is quite difficult to design at the present time. From the host of materials presently available, the prosthetic material recommended was "pyrolyte". This is based on current knowledge
regarding the reactions of "pyrolyte" in the blood system over a long period of time. The choice of pyrolyte as the most desirable material may change however as more data is obtained.

4.2.2 Investigation of magnetic therapy

Rehabilitation Medicine employs a number of technical procedures, which include physical methods of pain control, by use of deep heating modalities such as ultrasound. In the past short wave diathermy and microwave therapy have also been tried. Newer methods of pain treatment include use of Transcutaneous Nerve Stimulation (T.N.S.). Unfortunately, new modalities whose claimed results are difficult to verify may also be introduced to this branch of medicine. One such device is a "magnetic therapy unit", which on request of the Department of Rehabilitation Medicine, was investigated by the students.

It was in essence a limited device evaluation. The device in question was reported by its manufacturer to use "magnetic pulse stimulation" in the treatment of numerous physiological disorders. The theory of operation basically involved having affected area traversed by magnetic flux, the density of which was varied according to the disease.[11]

For treatment, the patient was to sit in a donut shaped apparatus, around which was wound a large coil, Figure 4.3. Power then is applied to the instrument, and magnetic flux generated. By dial selection, a low frequency current is delivered to the coil. Thus a pulsating magnetic field is generated on the
interior of the donut, where the patient or treated part is located. From this pulsating magnetic field, the manufacturer claims the following mechanism to take place.

When the whole body or single parts of the body are exposed to magnetic fields, the magnetic field lines permeate these completely. In doing so, the field lines meet sodium and potassium ions which are necessary for the functioning of the cell. Ions are charged carriers and are influenced by magnetic fields; by this the electric potential difference on the marginal surface of the cells is changed and the dynamics of the ions (exchange of ions between interior and exterior cell walls) is increased. The oxygen utilization of the cell is improved, which is the principle claimed medical effect of this method.[11]

The evaluation included the reading of literature on the known effects of magnetic stimulation therapy, as well as the "supportive" material provided by the manufacturer. From the background reading it was learned that beneficial effects have been observed, but mostly with osteogenesis, or bone growth.[4][23][30] Little information could be found to wholly support most of the claims of the device by the manufacturer. In many cases of claimed effects, absolutely no information could be found to support the manufacturer.

As to the material supplied by the company[12], much of it was discovered to be excerpts from noted, and not so well noted researchers
Figure 4-3: The "Elec" Magneto-Pulse apparatus. A new physical-therapy modality.
works. Often these were presented only so as to support the claims of the manufacturer (Appendix IV). Other literature was found to be nothing more than testimonials. From this literature pertaining to the device's operation then, the modality was felt to be highly suspicious. It was with much skepticism that, when given the opportunity, the students treated their first "hands-on" evaluation of the device.

Basically, the only "hands-on" evaluation of the device afforded the students was of an observatory nature. Essentially this involved the reading of the instruments "rating plates", a minor demonstration of its operation, and a chance to talk to a company representative. Even with such a limited introduction to the instrument, the students formed more questions about the operational claims made by the manufacturer.

First, on a plate located on the back of the device, the operating characteristics and warnings were found. In reading these operating characteristics, it was discovered that in the donut apparatus an operating temperature of 40 degrees Celsius could be considered normal. Due to the proximity of the patient to this area of the device, it would be easy for the patient to come in contact with a hot spot. Also, the reason for there being such an operating temperature could be questioned (the maximum output from the unit was a field of 100 hz. at 100 Gauss). When the sales representative was questioned about the operating temperature the answer given was that there was no need to worry
as such temperatures never occurred. This response raisedanimosity
towards the representative, and skepticism of the manufacturer's
ethics. Furthering the suspicion towards this person, and
her credibility as a Registered Nurse, was her apparent unfamilia-
ry with the term vaso-dilation (a physiological response
generated by the device, and a term which should be well known
to any nurse).

Since this device claims to cure physiological conditions
which are difficult to quantify, it cannot be stated that the
device is useless. However, the documentation of the claimed
results is inadequate. The sales representatives, although
meaning well, were not capable of giving a good understanding
of the device.

The suggestion made to the department concerned was that
the unit should not be used until better evidence of its claimed
effects are available. It was further proposed by a Physiothera-
pist that a group of patients be subjected to treatment with
this machine so effects can be validated or dismissed.

It is important to note that the "magneto-therapy" unit was
installed, after insistence by the manufacturers' representative,
on a temporary basis as a free trial. However, there were
no patients treated on the unit. The engineers' report, which
supported the impressions of the physicians in charge, resulted
in the equipment being removed from the hospitals premises
on the express wish of the department head.
4.2.3 Micro-Shock in the coronary care unit

Microshock is the accidental delivery of an electric current along a low impedance pathway to the heart. As a result of their direct application, even small currents in the range of tenths of micro amps, the heart can be caused to fibrillate.[8] The fibrillation is initiated due to the disruption of the hearts' prescribed electrical conducting system. The electrical conduction in the heart is noted to be of a strict pattern. The initiation of a heart-beat occurs in the sino-atrial (SA) node. From there it progresses down the conducting system; through the Atrio-Ventricular (AV) node, Bundle of His, bundle branches, and to the Purkinje network, causing each chamber of the heart to contract in the proper sequence.[10] In the event of a micro-shock, or any other electrical shock for that matter, this arranged sequence of events may be disrupted, and the heart may cease to function properly. Depending on the size of the shock (amplitude of current forced to flow through the heart) and the timing of the electrical "shock", this problem may or may not occur.

Small currents occurring during the "T" portion of the heart waveform (Figure 4.4) will cause the heart to go into ventricular fibrillation.[8] This is the crucial time when the ventricles are in the repolarizing stage.[5] The point to be considered is that even small currents are significant when there is a direct path to the patients heart. Hence, the reason why micro-shocks should be of major concern here.
Figure 4-4: An E.C.G. Waveform

It can be hypothesized that the problem of the delivery of a micro shock to a patient in the Coronary Care Unit, C.C.U. can occur. There are patients here who do have low impedance pathways directly to their heart. These are people who are fitted with a temporary pacemaker before a permanent one is surgically implanted. In these cases there is often connecting leads for the pacemaker which are in direct contact with the heart muscle. The terminals of these pacemakers lead to the outside of the body.

Keeping in mind that a low impedance pathway exists, and although the staff assigned to this area do take care with such patients, the question is posed as to whether a micro shock can be given to patients here? There are two main points
that must be considered for this analysis. First is the fact that in different hospitals, personnel in the C.C.U. were observed to handle the pacemaker leads with their bare hands. Consider also that the relative humidity of the C.C.U., for the hospitals interned at, are reportedly kept at between 30 and 70 percent. An analysis of the possibility of a hypothetical set of events culminating in the delivery of the micro-shock to the patient can be performed.

There are two possible ways that an electrical charge could be passed from a nurse to a cardiac patient. The first is to be a buildup of static charge on the nurse. If the nurse then holds the leads in each hand, any voltage on her body would be applied across the patients' heart. Although the possibility exists for such an event, it is felt to be highly improbable. This is because the relative humidity in these areas is from 30 to 70 percent. Therefore, there would be little chance for static charge to accumulate.

The second possibility of a voltage being applied across the patients' heart is due to ground potential differences.[24] This is defined as a difference in potential between two ground points. Due to the large numbers of equipment that are present in a hospital, large amounts of current are drawn from the mains causing equally large currents to flow in the ground wire of the "supply" line. Therefore, any resistance in the ground system can have a potential difference generated across it. For this reason, any two power outlets in the same room,
because they are not at the same point on the ground system, can have ground wires at different voltages. If the patient gets between this potential, as shown in the diagram and calculations on the next page, a current will be caused to flow. [24] This is felt to be the induced current that a patient in the above mentioned situation should be the most concerned about.

Normally the event of the second possibility is taken care of with special grounding systems for these high risk patient areas. However, cases can be cited where the intent of these special grounding systems are negated by improper workmanship during the renovations of such areas. [1]

The above analysis is felt to be warranted due to the possibility that patients in the past have been subjected to micro shocks. Several authors can be quoted as having expressed the suspicion that over the past two decades several such incidents of accidental micro shock have occurred. [8][24][32] Since there are high risk patients in these areas, with the possibility that they may go into ventricular fibrillation without the application of a micro shock, it is difficult to differentiate when a patient has fibrillated due to natural causes or because of some other phenomena. [8] There is a definite possibility that a micro shock may have resulted in ventricular fibrillation as it has been shown that currents of 180 microamps can cause ventricular fibrillation (depending on when in the cardiac cycle the shock occurs). [8] This amount of current can easily be generated in leakage current alone.
If circuit resistance of ground system = 1 ohm
If total load in one branch = 20 amps
then:

\[ V = 2 \text{ Volts} \]

This is the voltage at the distribution transformer, and is 2 volts above ground.

Consider now if the same condition exists in the other branch of a split 220 voltage circuit.
Since the two "hot" lines are normally 180 degrees out of phase, the voltage difference between the two grounds is 4 volts. Consider now a nurse who is touching one of the grounds while working on a cardiac patient who is connected to the ground of the other branch.

If the nominal resistance through the catheter and heart muscle of a coronary patient is 600 ohms; The current flowing through the heart would be:

\[ I = \frac{4v}{600 \text{ ohms}} = 6.7 \text{ ma} \]

This is 100 times the leakage current permitted in instruments used with cardiac patients.
4.2.4 Cardiac stimulator

One of the greatest assets of a Clinical Engineer was seen to be their ability to interact with and function as technologists. It is hypothesized that only with such teamwork between the technologists and the engineer can many problems in the hospital be solved. Although the intended function of the following example was more to give an introduction to some of the considerations necessary in the field of Cardiology, it does show how an interaction between technologists and engineers can lead to the solution of different problems.

The case in question involved an external cardiac stimulator. This instrument can be used to test the electrical characteristics of the "Bundle of His", the part of the heart's conductive system connecting the Atrio-ventricle node, A-V, and the Purkinje fibers of the ventricles. The experiment is done by artificially pacing the heart with a string of pulses.

The head of the Cardiology department, as mentioned, presented the problem to the students of developing a wiring diagram for a W.P.I Cardiac Stimulator to generate a desired stimulating pulse train. In order to preclude a long discussion of the different aspects involved with the study, a full report of the findings is included as Appendix V. To briefly summarize the findings, it was discovered that the desired pulse train could not be fully obtained. To realize the optimum pulse train, an external trigger circuit would have to be constructed. This is presented in
Appendix V.

This example brought to light one important aspect of many pieces of medical instrumentation. To meet C.S.A. standards pertaining to leakage current, many devices use battery power supplies. The objective is to reduce the grounding and leakage current problems. This does create the necessity of constantly having to check the batteries to insure they are still charged. A battery problem also plagued the successful test of Bundle of His, as described.

In this device, the batteries when under load would not work since they had become old and weak. It was discovered that no backup power supply for the unit was to be found in the hospital. To get a replacement set of batteries would require a waiting period of up to six months. Because of this, it was suggested to the doctor using the unit that a further alteration be made to the device. The type of power supply used could be changed from the currently used dry cells to rechargeable cells. Though costly, it would eliminate the problem of the power supply becoming nonfunctional for long periods of time.

These were four areas in which the students applied their abilities to medical research and instrument evaluation. From each, the student was exposed to different aspects of device evaluation and research consultation. Also, the student learned of the benefits that can be derived by having a concentrated department consisting of Electronics Technologists and the
Clinical Engineer.

4.3 Repair modification and calibration

Due to several different reasons, the students had the chance to see different aspects of equipment management which they may have to deal with as Clinical Engineers. These involved the area of equipment repair, making equipment modification, and calibration.

These areas are falling more and more into the realm of a Clinical Engineer due to two main reasons:

1. The means presently used to take care of these factors (service contracts) are becoming less acceptable to the hospitals. This is due to the down-time and cost involved.

2. Many pieces of equipment are too small for the manufacturers to offer service contracts. Alternatively, the equipment is not of high enough priority for the manufacturers to give immediate attention to in the event of a breakdown.

Because one of the hospitals the students visited was moving away from service contracts and employing their own in-house Biomedical staff, the students were permitted to observe how equipment failures and other equipment management aspects were handled. In some cases the students were allowed to perform the device checks themselves. The following paragraphs summarize a few of these experiences.

4.3.1 Oxygen monitors

In the Operating Room the Anesthetist may use a device to
monitor the percent oxygen being delivered to the patient during an operation. The main component of these devices is a specially designed galvanic cell. The following are the principles of operation for these cells.

The cell utilizes a silver cathode, lead anode, and potassium hydroxide electrolyte. Oxygen is admitted to the cell through a teflon membrane that is permeable to the gas but not the electrolyte. Oxygen is reduced at the cathode to produce hydroxyl ions, in a reaction catalyzed by the silver. These ions combine with lead at the anode to form lead hydroxide. The electron flow from the lead to the silver electrode through a micro-ammeter is a measure of the rate at which the reaction proceeds. Hence, it is a measure of the percent oxygen in the anesthetic gas. The process therefore measures the percentage of oxygen as a function of the ammeter indication.[24]

During the time spent with the Anesthetist in the O.R., it was found that all but one of these oxygen monitors were in-operative. Upon inspection, it was learned that the cells had become inoperative because they had dried out. Further investigation revealed that the cause of the problem was due to the units being constantly left on. This resulted in a depletion of the chemical activity previously described. It was learned that the cells themselves were quite expensive, making it uneconomical to maintain a large supply of the cells by the department. Also, although it is not know for sure, the "shelf"
life of the cells may not have permitted the necessary "stock-piling".

A possible solution to the problem might be to have the unit cycle off after two or three hours of operation, sounding an alarm before turning off. It was felt that this amount of time would be long enough for most of the short operations to end before the device cycled off. However, should it turn off before the operation had finished, the Anesthetist, upon hearing the alarm could turn the instrument back on. Thus there is a rather simple solution to a potentially costly problem. Such a proposed modification though is realized to be possible only though co-operation with the manufacturer of the monitors.

4.3.2 The H/P 1533A system

Located in the Electrocardiographic (E.C.G.) Lab is the Hewlett Packard 1533A system. This system is used to deliver E.C.G. tracings from different areas in the hospital to the E.C.G. laboratory. The purpose of the system is to transmit the E.C.G. tracings to the lab via the telephone lines, as opposed to having the technician carry these traces there. In theory, if the system were operating properly, this method of delivering the traces to the lab where the actual reading of the E.C.G.s is done has many desirable points. Most importantly, the chance of "traces" being misplaced as a result of their transport to the lab would decrease. Also the traces are delivered directly to the lab as soon as they are taken. Unfortunately these advantages are only
effective if the system is operating properly.

During the students stay in the Cardiology Department (with which the E.C.C. Lab is associated) this system was totally inoperative. The fact that the company service representative would not be available for some period of time prompted the department head to give the students the job of discovering the fault. The head of the Cardiology Department requested that the results of this investigation be submitted to him in the form of a report so an accurate account of the findings could be made. A revision of the report submitted to the Cardiology Department summarizing the results found, and recommendations made is included in the report found in Appendix VI.

The investigation on this piece of apparatus uncovered a number of other undesirable characteristics in this department. A list of problems found within this department has been included as part of the report in Appendix VI. A few of the major problems that cropped up from this investigation are also common to several other areas of the hospital.

The first of two major problems observed was related to the uncertainties about the operation and reliability of the system on the part of the technicians operating it. Many of these problems have been mentioned earlier, and are included in the report. Therefore, these aspects will not be discussed again other than to indicate that the presence of a Clinical Engineer might have allayed suspicions about the reliability of the
system. This would be by allowing the technicians to access technical personnel when problems or questions arise from the operation of the system.

The second major problem arises from Service Contracts. This is the system mentioned earlier that is frequently used by the hospital for medical instrumentation management. This is also the means by which the above system was maintained. The problem with such a mechanism for overseeing medical equipment is that long "down times" can occur. This problem with Service Contracts may be due to the company service person having higher priorities on his list. In the case of the E.C.G. collection system the service person's position was tolerable because the system was not high on the departments priority list. Therefore, the period of time before the service person attended to this system was lengthy. The point to be made is that an expensive system was inoperative for a lengthy period of time challenging its purpose for existing in the first place.

It is suggested that a solution to this problem, is to have an "in-house staff" with enough technical capability to handle such system break-downs. This is a general solution, applicable to other equipment found in the hospital. Such a method of instrumentation maintenance would be more desirable as the necessary service people would be in the hospital at all times. Also, the responsibility of ensuring the equipment is operational as much as possible would not be with the "heads of the
Therefore the "push" necessary to ensure that all the equipment was well maintained should be always present. The specific remedies to the problem observed with the E.C.G. data collection system are mentioned in Appendix VI.

4.3.3 Device calibration and modification

Device calibration and modification should demand a lot of the Clinical Engineers' time. This demand has been prompted by economics. That is, many hospitals are finding it is necessary to retain much of their present equipment, even though better replacements are available. The problem is that there is not enough "capital" in the health care system to permit large scale hospital instrumentation replacements. Also, with the rapid advancements being made in technology, experience has taught the hospital administrators that a piece of equipment they buy today will probably be outdated by the time it can be installed. Alternatively, the proper authorities may not be aware of the state that some of the equipment had reached. This degeneration of the equipment may be due either to neglect or simple obsolescence. Whatever the reason, a number of examples can be given to justify the need for a competent person to look after device calibration and modification. First, consider the problem of device calibration.

Many of the hospital instruments that were dealt with had been in place for a long period of time. This often ranged from two to four years, and longer. It was observed that most of the
non-technically minded persons using such instruments believed an output was all that was necessary to verify an instrument's proper operation. In two of the Health Centers visited no Preventative Maintenance (P.M.) checks were being done on a regular basis, during the time of the internship. For these institutes then, no recalibration of many medical instruments were taking place unless the unit totally breaks down. Hence no real check was made to see if the machines' outputs are accurate. This practice was observed for all departments except the critical care areas, where periodic checks are performed. But these were for leakage current only.

An example of where such a problem surfaced was in an O.R.. This occurred during an open heart surgery and involved the temperature monitoring of a patient. In this case, two different temperatures were being taken. One was with the probe inserted orally, to measure the patients' trunk temperature. The second temperature was obtained from the blood as it was recirculated through the "heart lung" machine.

The operation required that the patients' heart be bypassed. Also the patient was put into hypothermia (severe loss of heat) to reduce the motions of the heart. This was done by cooling the exterior of the heart by immersing it in a fluid cooled to 4 degrees celsius. The temperature of the blood being circulated by the heart-lung machine was also lowered. Such a procedure should have resulted in the patients' body temperature being drastically
In the student's opinion, a problem arose after the patient was placed on the heart-lung machine for several minutes. At this time the temperature monitor monitoring the circulating blood indicated 16 degrees Celsius. From physiology, a rule of thumb says that the trunk temperature should be about 6 degrees warmer (in this case 21 degrees Celsius) than the circulating blood temperature. However, the temperature monitor on the anesthetic machine indicated a patient temperature of 29 degrees Celsius. It is realized that the above rule of thumb is just that, an approximation and is subject to inconsistencies. However, an observation by the student was that the temperature indicated by the monitor felt to be in error never did indicate a temperature lower than 29 degrees Celsius, even though the blood was continued to be cooled.

No major complication was observed to result from the hypothesized instrument problem. However, the incident may indicate a problem in the instrumentation management for the O.R.. This was the conclusion reached by the student when he discovered that the last safety check, as indicated by the safety inspection sticker on the device, for the anesthetic machine had been made two years previous to this incident. Further investigation revealed that actual calibrations of the hospital's instruments' output variables were not done in these institutions unless such obvious inconsistencies as that just described arose.
If time permitted further examples of the observed need for a more rigorous medical instrument repair and calibration program could be given.

The second of the two topics concerns instrument modification. This is becoming an important area with medical instruments. This is true not only because the manufacturers themselves are suggesting modifications to their products, but also due to the process of medical metrification.

The first reason for the modifications has been due to manufacturers suggestions. These alterations are requested by the manufacturer because of results received during the devices operation in the clinical environment. That is, based on clinical trials, the manufacturer has come up with methods of improving the operation of his equipment. The second reason for the trend in equipment modification has come about because of the current move in Canada for all hospitals to metrificate. This is a factor that many manufacturers may not have taken into account when they designed their original products.

Most hospital equipment output their results in old English units, or some other non standard set of units. The problem of converting these outputs to the more standard metric system exists. This is one problem the students were faced with in the Hematology lab with the Hemalog 8(Tradename). In particular, they were asked to investigate the possibility of converting the output results of this instrument into metric units. It was hoped
that this could be done simply by making a hardware change with the existing equipment circuitry.

After reviewing the circuit diagrams for this device, and following the manufacturers suggested modifications, the change necessary to obtain metric outputs would be quite simple. In fact, basically all that was required was the insertion of two jumper wires onto an already existing circuit board. To most technically minded personnel this would be an extremely simple operation.

However permission for this modification was not obtained. The reason given was that the possibility existed for something to be knocked loose on the circuit board if the alteration was made. On first glance, this seemed to be the response of an over cautious administrator. However it should be noted that this cautious attitude may have been warranted for three reasons. First is the fact that this was the only device in the hospital with the capability to automatically perform the relevant blood tests. Secondly, the head of this department may not have had confidence abilities of the students abilities, an important point that any Clinical Engineer must strive for. Finally, the instrument did have a very heavy work load. Therefore, if it was working, then possibly it shouldn't be tampered with. However, the insertion of two jumper wires should never cause problems to be generated with the circuit, provided all precautions are taken.

To reiterate, the modifications were suggested by the
manufacturer. Also, the students reviewed the circuit diagrams, checking to insure that these jumpers would not be placed in an area that would result in circuit problems (for example, a short circuit). It is felt that these modifications should have been attempted.

Each of the examples given above are ones which a Clinical Engineer can expect to see in his profession. These are to be expected, given the function they are to perform and the rapid developments occurring with medical instrumentation.

Given that Clinical Engineering is a new discipline (especially in Canada) there has been a significant period of time in which the Health Care Industry has had the opportunity to develop bad habits. These are also things that the Clinical Engineer will have to deal with.

During the internship, several cases of poor engineering practices and instrument management were observed. A short section based on conditions observed in four major health centers will now be given. These should be representative of what can exist in other hospitals due to the medical equipment maintenance systems employed by each.

4.3.4 Instrumentation management problems

In most hospital centers, one can expect to see poor works of engineering and other forms of instrumentation problems. However, given an efficient Biomedical Electronics Department, it
is felt that many of these should be able to be dealt with.

The reason for these instrumentation "problems" may be due to any one of a number of factors. Four of the more probable reasons for their existence are as follows: instrument design faults, building design faults, temporary instrument repairs being made by unqualified personnel, or an electronics department which is unclearly defined. If these problems are not considered or dealt with, it is felt that they can culminate in disaster.

In two of the centers attended by the students, several cases of equipment management problems were observed. One important factor promoting the existence of these problems is felt to be the lack of a well defined Biomedical Electronics shop in these hospitals. This definition is required so that the personnel in the department are aware of the function they are to perform. As a suggestion, the functions of the Biomedical Electronics Department may range from the design of some medical systems (equipment related), to supplying input on the design of different areas of the hospital, to helping teach current hospital personnel some of the more technically related aspects of the instrumentation they will use. This proposal can be substantiated by considering the following examples from the Clinical Engineering internship.

In all but one of the hospitals visited some amount of construction or renovation was in progress. In some of the cases, the construction was being performed for a well defined reason.
In most areas of the hospital, proper consultation was obtained before the actual blue prints were drawn up. This allowed the designers to have a better idea of the functions in a given area, allowing them to modify their design accordingly. However, in all the hospitals the actual design and construction of the facilities was performed by personnel unacquainted with hospital building requirements, or area function. Therefore, faults in the hospital can occur due to a lack of proper initial consultation or oversights of pertinent medical instrumentation standards. These are the kinds of facilities Clinical Engineers are going to work in. These will often hamper certain goals pertaining to medical instrument performance and decrease department efficiency. As a result, a suggestion may be that in areas where medical instrumentation will be used that the advise of a Clinical Engineer, whose responsibility is to know the necessary "standards" and instrument operating principles being used, be sought.

An example of where design oversights occurred was observed in one of the health centers interned at. It is pointed out that the particular hospital in question was under renovation during the internship and the problem cited, as of the time of the writing of this report, in all probability has been rectified. The incident occurred in a proposed new neonatal unit. This is an area set aside for the monitoring and patient support of premature babies. The design fault observed, if it were not corrected, could ultimately lead to disastrous or expensive
The problem concerned leakage current monitors, or ground fault detectors. Specifically, the renovation design for the neonatal unit had called for four monitoring stations (one neonate per station, on the same leakage current monitor). The entire unit itself contained four such monitors, each providing surveillance for four stations. The observed situation was noted to contradict some of the standards outlined by the Canadian Standards Association (C.S.A.).[6]

Two basic aspects of the designed area were felt to be at fault according to the C.S.A. standards presented in the Standards publication, "z32.1". First was the distance between some beds and the respective leakage current monitor, (C.S.A. Standard z32.1 section 5.4.3.4)[6] which was seen to be in excess of 15 feet. This has the effect of increasing the capacitive leakage (current) between the "supply conductors" and the ground wire.

The second problem with the observed design involved the total amount of medical instrumentation that would have had to be monitored by each leakage current monitor. It is noted that every monitoring station for a neonate can have a large amount of equipment assigned to it to help the neonate survive. It should be understood that each neonate can require a respirator, E.C.G. and pressure monitors, and a heat lamp. Multiply this by four and the equipment can generate a large amount of leakage current for one monitor.
It was observed in this proposed area then at the time of the internship that even before any of this equipment was connected, some of the leakage current monitors were already reading two thirds full scale.\[1\] The large leakage current observed is felt to be as a direct result of the first problem mentioned above. The second design fault, of having too much equipment monitored by one leakage current monitor, is believed to permit the definite possibility of major amounts of leakage current to flow in each monitor. This is especially true when coupled with the problem of the long cables observed to connect some of the beds with their respective monitors. The net result is a contradiction of the permissible leakage current as specified in C.S.A. standards publication "z32.1" (section 5.4.3.5.1.).\[6\]

Any solution to the problems would be costly. One proposal would be to remove the leakage current monitors all together. However, in the event of an infant death there would be no knowledge of what the leakage current was at the time. Such a proposal would also leave the hospital liable to legal prosecution. Secondly, without leakage monitors, the hospital would not be able to get its government issued operating license. Therefore, such a proposal is impossible. Alternatively, the area could be re-renovated, putting each monitoring station on its own leakage current monitor. This is believed to be the recourse that was taken by the hospital in question to solve the design problem.
The Clinical Engineer may also be of assistance to different departments of the hospital by assisting in the choosing of the instruments to be used by the departments. Since the Engineer would be more qualified to give an opinion on the technical limitations of the device, from the engineering point of view, by complementing the physicians knowledge of the intended use of the instrument a more sound decision on the system purchased could be made.

When a hospital decides to implement some new system it may be advantageous to perform a joint investigation, similar to that described in the previous paragraph, on the systems that may be purchased. In some cases, the quick choice of an instrument could leave the hospital with a device that will do what is expected and desired. It is therefore proposed that with the technical consultation that would be provided by a Clinical Engineer, Hospital Department Heads could receive additional, helpful, input as to the piece of instrumentation that will meet their needs.

The two points mentioned above indicate how an input by a Clinical Engineer may help in the solving of some instrumentation management problems present in today's hospital. Two of the remaining three proposed sources of faults in the Health Care System are more difficult to rectify. These are the areas of instrument design faults, and the temporary repair of instruments by unqualified personnel.
The problem of instrument related faults poses less of a problem. Although the number of problems generated by design errors has not lessened, many reputable medical instrumentation manufacturers are most eager to help in overcoming problems attributed to their equipment. Therefore, in the event of an instrument breakdown, these manufacturers will supply "loaner" substitutes for the inoperative device. In the event of major shortcomings in the manufacturers product (as evidenced by clinical trials), the manufacturer will take strides to remove these faults from the device.

Such a case was seen to occur with infusion pumps, or specifically with the IVAC infusion pumps. The major problems existed due to the design of the device. For example, with this instrument it was difficult to tell if the hose inside the device had collapsed or not. This has caused the anesthetist concern when no blood or other Intra-Venous fluid could be administered to the patient, and no visible explanation available.

The manufacturers of this device have been constantly searching to better their product. This has been to the extent that complaints have lessened and Infusion Pumps as a whole have moved from the top of the medical device problems list.[17]

The problem concerning attempted repairs by unqualified personnel will always be present in the hospital. The reasons for this problem are untimely equipment malfunctions during peak work times. Under such circumstances, the plight of the technician or
other operator can be appreciated. That is, under the pressure of a heavy work load, the operator will always try to get the instrument operating again, no matter what the technique. To resolve this problem, it is suggested that a good Preventative Maintenance (P.M.) program should overcome several of these occurrences.

This aspect of a preventative maintenance program however brings up the fourth and final area of the Health Care Industry where engineering problems exist. That is, in order to have a good P.M., the hospital must first have a well defined Biomedical Electronics Department. It is proposed that one of the functions of this department would be to institute, co-ordinate, and maintain such a P.M. system.

A successful department similar to the one suggested above was observed in one of the four health centers visited. On the other hand, at least one of the other three hospitals did not have its Electronics Department particularly well defined. Thus, a contrast could and was be made between the two departments. Many advantages of simply having an Electronics Department in the hospital were also observed. Some of these are as follows:

First, the administration of the proposed P.M. schedule for instrumentation, could be done from a central office. Second, a well defined department could limit its activities only to those relevant to medical instrumentation. Thus, functions such as those seen for one of the departments, where the technologist
gave equal priority to the repair of a television, tape recorder, and an Intra Aortic Balloon Pump, would not exist. Such a diversity of activities does not promote any expertise with respect to the first two pieces of equipment, let alone medical instrumentation for which this report suggests should be the primary concern of the department.

A third advantage of a well operated Electronics Department would be the concentration of technical personnel more highly qualified in the area of medical instrumentation. Hence, limiting its scope of expertise to medical instrumentation only, the ability to handle most of the problems associated with the varied pieces of equipment would, it is proposed, be generated.

Finally, such a well defined group could be delegated authority for several other aspects of instrumentation. For instance, a company sales representative could deal with this department in conjunction with the individual medical departments when trying to sell their equipment. The advantages of having input from the Clinical Engineer shortly after the need for the instrumentation are identified and approved would be two fold.

First, the manufacturer could be questioned about the technical aspects of his device. This could be done to check technical points of the equipment. Such input would be in the form of consultation, and only at the request of the Department Heads or the hospital administering body.
Second, the department, acting as a library, could be responsible for obtaining and keeping literature pertaining to medical devices located in the hospital. This is a definite requirement for the implementation of a P.M. schedule. That is, in order to set up any sort of a P.M. schedule, the personnel must be supplied with the manuals for the devices for which they are responsible.

The above paragraphs have attempted to indicate some of the irregularities in hospital instrumentation management. These problems have been highlighted by actual examples of the present management difficulties and needs observed in hospitals during the internship. In response to these observations, this chapter has attempted to show support for the suggestion that such technically trained personnel as Clinical Engineers and Physicists be more widely used by hospitals.

Through the points made in this chapter an attempt has been made to indicate some of the areas of medical instrumentation where the Clinical Engineers may be involved. These included areas not listed in the seven functions of the Clinical Engineer, as outlined in Chapter 2. However, by no means is that list complete. Other areas of the hospital operation will undoubtedly receive input from the Clinical Engineer in the future.

A further example of where the Engineer may be asked to provide an input is in the area of department layout. This would be so as to capitalize on the Clinical Engineers knowledge of the
instrumentation to be used in these areas and the pertinent instrumentation "standards" to be met. Further, due to a possible lack of a Rehabilitation Engineer, the Clinical Engineer may find that he is needed by a Rehabilitation Department for consultation. This in fact could be a full time position in itself.

This chapter coupled with the previous chapter show that the students involved in the internship found many engineering problems to which they could apply their skills. It also indicated to them that the need for Clinical Engineers exists in the modern Canadian hospital.
5. EXISTING METHODS OF MEDICAL INSTRUMENTATION MANAGEMENT

In the preceding chapter an argument was made regarding the need for technically qualified personnel. This requirement is due to today's need for better medical instrumentation management.

Also in the last chapter, it was suggested that in the future, this aspect of the health care industry would be administrated largely by a Clinical Engineer, in co-operation with the present hospital staff and in control of a Biomedical Electronics Department. Such a department, would combine the practical abilities of dedicated technologists, with the theoretical and professional capabilities of the engineer. Although this is the direction that instrument management appears to be going, these are presently maintained by personnel other than the Clinical Engineer. These included three main groups of people. Portions of the equipment management operations are presently performed by: in-department expertise, service contracts, and in-house Biomedical Electronics Department.

5.1 In-department expertise

During the internship, it was observed that at least two departments in the hospital found it necessary to employ specialized professionals for their instrumentation management. This was due to the highly scientific principles involved with the equipment used there. These two departments were Radiotherapy (using nuclear particles) and Pathology (using complex chemistry).
In Chapter 3 of this report an indication of the procedures and equipments used by these departments was given. Because of the dependence of these departments on physics and chemistry, they have found it necessary to have a physicist (in the case of Radiotherapy) and chemists (in the case of Chemical Pathology) on staff. In these areas of the hospital it is these people that have been primarily concerned with equipment management. This includes all instrumentation related aspects as outlined earlier in this report. These two groups of people generally dedicated to the specific equipment needs for their respective departments.

During the Internship in the Radiotherapy department, the use of many complex nuclear physics principles were observed. These principles were applied to the treatment of cancer, and the acquisition of diagnostic images of a living body. Due to this complexity, medicine has turned to the physicist for help. Since the first use of high speed particles in medicine, the physicist has been in the hospital instructing the "traditional medical staff" about the physics they were using. This was with respect to the principles involved in the treatments they were administering, as well as the operation of the equipment they were to be using.

Because the physicists have been around since the inception of the Radiotherapy and Nuclear Medicine Departments, they have had ample time to develop Instrument Management programs. This was as seen during the internship. As mentioned, the management they
provide has been with respect to most of the seven points mentioned in Chapter 2. These include the overseeing of equipment repairs and modifications, teaching of medical staff and acting as consultants for the administrators. They also act as liaison between the department and the manufacturers. It must be remembered that the equipment involved here is significant in size, cost and complexity. Thus, the onus has been on the physicist to generate good and efficient equipment management methods.

The equipment the physicists are most concerned with is limited to those using high speed nuclear particles or ultrasonics. However, the programs they have set up in this department can be of great benefit to the Clinical Engineer, or any other person involved in similar programs in other departments. In fact, it can be said that the services provided by the physicist to the Radiotherapy Department are exactly the type the Biomedical Electronics Department should supply to others.

An example similar to the one given for the physicist in Radiotherapy or Nuclear Medicine can be applied to the chemist in the Pathology Department. Just as the physicist was primarily concerned with one specific application of high speed particles in medicine, the chemist is similarly concerned with one particular area of the Pathology Department. This, of course, is the Chemical Pathology section.

Because a high degree of chemistry is used in analyzing human
fluids and tissues, a need for Chemists has been generated. Unlike the physicist, the chemist has not had to develop a program which encompasses equipment management for the whole department. Rather, each chemist was more concerned with one particular aspect of the department. For instance, one chemist was responsible for the operation and care of the chromatography and spectrophotometry equipments. This meant that he developed the preventative maintenance schedule for his own apparatus only. This of course would be in conjunction with the manufacturers own preventative maintenance program. Although quite different from the system used in Radiology by the physicist, this method of equipment management was observed to be quite efficient and adequate.

By having trained professionals in the department several additional benefits have been realized. First, by having privileged access to this group of people, these two departments were able to operate more efficiently as a whole. Secondly, the hospital staff associated with these departments appeared to be more self confident. This may be due to the on-going education derived from in-house experts. Also, when a major problem arises, these experts can be immediately asked to lend their expertise to solve the problem. Finally, with physicists in the department, the feasibility of applying nuclear physics to other areas of medicine can readily be conducted. It must be pointed out that although these individuals do a lot towards making the departments generally more self sufficient, with respect to
instrumentation management, even the physicists and chemists have their limitations. Therefore, a second method of equipment management is necessary for the hospital.

With the high technology equipment used in these departments, as well as the instrumentation used in other areas of the hospital, the Health Care Industry has found it necessary to use a second method to maintain its equipment. This is done by paying the manufacturers to provide maintenance and consultation for the equipment they produce. This arrangement is referred to as a service contract.

5.2 Service contracts

The hospital administration has found service contracts appealing in many ways. As a result they have become quite popular as a means of maintaining hospital equipment. The service contract method has the manufacturer provide any maintenance necessary for the repair of equipment sold to the hospital. The extent to which this is done, as well as the means by which it will be done varies from contract to contract and from device to device.

For most pieces of equipment encountered in the hospital, a service contract can be purchased. This excludes some low cost portable devices such as finger plethysmographs which are simply replaced when they cease to function. For the larger pieces of equipment, the differences between the contracts available for a piece of equipment vary with respect to the services that the
manufacturer will guarantee, as well as the cost of the contract. The most significant area of differentiation between the types of contracts available is with respect to who will perform the repairs and where.[22]

First, the manufacturer will sell a contract that provides "on-site" service by their own service personnel. Such a contract guarantees that in the event that the manufactured piece of equipment fails, a qualified person from the regional office will make the necessary repairs. This contract covers only the labor and certain device components that may fail. As indicated above, different levels of this type of contract can also be bought. These differ with respect to the guaranteed maximum response time taken by the service person to arrive. The premiums charged are directly related to response times. When dealing with distant companies, the response time plus the high cost pose major disadvantages.[22]

A second major contract option involves a "mail-in" service on portable equipment, with "loaner" units supplied sometimes. In addition, the manufacturer often guarantees parts delivery or an attempt at parts delivery, with some department in the hospital doing the actual labor. Such a contract has the potential for providing many of the advantages mentioned earlier. The key point to the contract is that "on-site" repairs are done by a department located in the hospital. With an "in-house" department of qualified technical personnel, teaching and other aspects of
equipment management are the responsibility of that department. Theoretically, these functions are performed. However, this would only be true if that department is well defined and operated. These are the major forms of service contracts used in the hospital.[22]

Besides the drawbacks and potential problems with service contracts, different advantages are also seen for hospital administrators. First, they guarantee the completion of all field updates and equipment enhancements (mentioned in Chapter 4), updated software, and perhaps contracts that allow access to otherwise unobtainable information. Such services, coupled with those mentioned above, make for a very appealing option to administration. These, however, are not all that make this form of instrumentation management enticing. The four aspects that follow also lend to the service contract argument:[22]

1. Service contracts assure continuity of service or facility, theoretically.
2. They are cost effective when dealing with high value equipment and components.
3. They are often the only option when dealing with high technology and the absence of an in house servicing capability.
4. They are very budgetable in that they allow for known expenses.

With all of the above points for service contracts taken into consideration, one may wonder why this is not the universal method used for equipment management. A number of answers are
available to this question.

First, there is the administering of the seven points outlined in Chapter 2 as presently requiring attention in the hospital. None of the contracts just mentioned provides for all of these considerations. Second, and like most aspects of today's society, the costs of service contracts are of importance. Generally, such contracts can cost in the order of 7 percent to 15 percent of the original equipment cost per annum.[22] Therefore, with hospital equipment ranging from tens to hundreds of thousands of dollars this cost of service contracts as a form of equipment management can be quite significant. These facts tend to enhance an alternative form of hospital instrumentation management. This alternative is for the hospital to employ its own Biomedical Electronics Department. If such a department were kept properly staffed and trained, the hospital would realize a minimum of costly services contracts.

5.3 In-house biomedical electronics department

The third type of personnel presently performing the function of medical instrumentation management is one which operates as a branch of the Engineering and Maintenance Department. In the internship, this branch was seen to be referred to as the Electronics Department. The department is comprised of technicians and technologists, under the supervision of a manager, who in turn reports directly to the hospital Engineering Department.
The functions performed by this department are mainly in the form of repairs. Very few of the seven points mentioned in Chapter 2 were seen to be performed here. Additionally, with no clear definition, such a department becomes an area for general electrical repairs. As mention in Chapter 4, this can include televisions, micro-wave ovens, and tape recorders. These activities would be in addition to biomedical instrumentation repairs.

In the author's opinion, this third organization has definite limitations in its attempts to administer to the needs of hospital equipment. This stems from the fact that the head of the department cannot devote his full attention to the needs of that department. Also, at least for the Electronics Department, these areas of the hospital appear to be rarely given a clear definition of their responsibilities. These two problems can be seen to hamper the department when dealing not only with the hospital staff, but also with suppliers and manufacturers.

This last point is of extreme importance since the manufacturer reserves the right to look after his own service departments first, with respect to components and other electronic equipment.[22] Hence, a department with no clear voice can be at a definite loss at obtaining supplies. Some Electronics Departments have obtained a clear voice in the hospital. This has been largely due to its disassociation from the Maintenance Department. With more control over its own operation, it has been
observed that such Electronics Departments, properly staffed, can fulfil most of the aforementioned seven points of Chapter 2.

This concludes the observed methods presently used by hospitals to manage their equipment. Some of these methods have advantages over others. It is suggested, as in Chapter 4, that by combining the positive aspects of all four of these methods into the department of a Clinical Engineering, optimum efficiency can be realized. That is, a Clinical Engineer with his expertise in the applied sciences, and aided by a well outfitted Biomedical Electronics Department, can fulfill all the points suggested as being important in this field of medical instrumentation management.
6. CONCLUSION

Medical instrumentation management in the hospital is demanding more and more attention from the Health Care Administrators. The most significant reason for this is the rapid advancements made in the field of medical technology. This rapid development has left hospital administrators confronted with the problem of deciding how best to handle this aspect of health care.

The generation of the position of Clinical Engineering in the hospital is a suggested solution to the question of equipment management. This alternative is one that is viewed with seriousness today, that a formal course in Clinical Engineering is now offered in the attempt to train personnel for this position. The course is offered to certain branches of engineering, and is geared at enhancing the individuals appreciation of the clinical environment, while capitalizing on scientific abilities. It is from this course and its included internship in the hospital, that the material for this report was obtained.

At the outset of the report, seven activities of the Health Care System were suggested as being prime areas of concern for the Clinical Engineers. Further, it was indicated that a dire need to confront these exact problems already exist in the hospital. Finally, it was outlined how the choice of a Clinical Engineer as a medical instrumentation manager would benefit the hospital.
Some of the present methods used for equipment management were reviewed. Given this review, the job suggested to be performed by the Clinical Engineer would be quite similar to that performed already by the physicist in the Radiotherapy Department. This is to the extent that the Clinical Engineer could build his operations around the example set by the physicist.

Of the other methods used by the hospital to manage equipment, the form having the Electronics Division under the direct supervision of the Maintenance Department was felt to be the most undesirable. The reason for this observation is that the needs and functions of a Biomedical Electronics Department are quite different from those encountered in the other sectors of a Maintenance Department. In order to handle the problems that can arise with the complex medical instrumentation the technical abilities of the personnel of this department are taken to the limit.

It is realized that with the control of the Electronics Division in the hands of the Maintenance Departments' administrator, the Electronics staff must operate in competition with the concerns of houskeepers, mechanics and the rest of the personnel of a Maintenance Department. It is therefore felt that the concerns and capabilities required of the complex field of medical instrumentation management are not dealt with to an optimum degree. This is not to say that the administrator of the Maintenance Department should have no input on the operation of
the Biomedical Department. Rather, with a Clinical Engineer as the director of the Biomedical Department working in conjunction with the director of the Maintenance Department, it is felt that a better overall maintenance service can be provided to the hospital.

It was also pointed out in this report that the lack of a clear definition of the function of the department prohibits its optimum development. Given that the Clinical Engineer acts as the manager of this department and controls the other aspects of equipment management in the hospital, it is suggested that such a problem would be alleviated.

It is felt that a strong argument is made by this report for having an in-house department with technically capable personnel. The suggested structure of the department given by the report would have a well defined and operated Biomedical Electronics Department headed by a Clinical Engineer. It is further proposed that limited service contracts should be incorporated into the operation of this department. The reason for this final suggestion is that it allows access to otherwise hard to acquire information, and it is the most economical method of caring for some of the extremely high technological equipment found in the hospital.

One major observation was made from the internship. This observation has been stressed throughout this report. Specifically, this is that a definite and immediate need exists
for an in-house Biomedical Department. It is further suggested that the optimal structure of the department would have a Clinical Engineer as its director. Thus arises the need for Clinical Engineers in Canada today.
APPENDIX
I. COURSE OUTLINE FOR THE CLINICAL ENGINEERING DEGREE

It is pointed out that like the Biomedical Engineering Degree, the Clinical Engineering Degree is an interdisciplinary degree. As such, the courses that can be taken for the degree can be from most any of the departments on campus. However a sixty to forty ratio of engineering classes to non-engineering classes is strongly recommended. With such a format, within limits then, any combination of classes can be applied towards the Masters of Engineering in Clinical Engineering Degree. The following is a sample program, similar to the one that the author took, for the Clinical Engineering Degree.

<table>
<thead>
<tr>
<th>Selected Topics in Biomedical Engineering</th>
<th>Suggested</th>
<th>Term Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomaterials</td>
<td>Suggested</td>
<td>Term Course</td>
</tr>
<tr>
<td>Physiology</td>
<td>Essential</td>
<td>Full year Course</td>
</tr>
<tr>
<td>Image Processing</td>
<td>Elective</td>
<td>Term Course</td>
</tr>
<tr>
<td>Interpretation of Electrocardiograms</td>
<td>Elective</td>
<td>Term Course</td>
</tr>
<tr>
<td>Radiology in Medicine</td>
<td>Suggested</td>
<td>Term Course</td>
</tr>
<tr>
<td>Passive Filter Design</td>
<td>Elective</td>
<td>Term Course</td>
</tr>
<tr>
<td>Health Care Management</td>
<td>Elective</td>
<td>Term Course</td>
</tr>
<tr>
<td>Project Course</td>
<td>Suggested</td>
<td>Full year Course</td>
</tr>
<tr>
<td>Selected Topics In Instrumentation</td>
<td>Elective</td>
<td>Term Course</td>
</tr>
<tr>
<td>Introduction to Medium Size Computers</td>
<td>Essential</td>
<td>Term Course</td>
</tr>
</tbody>
</table>
As mentioned above, this is but a sample program, with an endless list of possible variations.
## II. CLINICAL ENGINEERING INTERNSHIP SCHEDULE

<table>
<thead>
<tr>
<th>DEPARTMENT</th>
<th>ASSOCIATED AREAS</th>
<th>DURATION OF ROTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary Medicine</td>
<td>Respiratory Technology</td>
<td>Three Weeks</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>Operating Room</td>
<td>Four Weeks</td>
</tr>
<tr>
<td></td>
<td>Electronics Department</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>Hemodynamics Lab</td>
<td>Four Weeks</td>
</tr>
<tr>
<td></td>
<td>E.C.G. Lab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Echocardiographic Lab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stress Test Lab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical Care Areas</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>Ultrasound</td>
<td>Six Weeks</td>
</tr>
<tr>
<td></td>
<td>Radiology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nuclear Medicine</td>
<td></td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>Children's Rehab. Center</td>
<td>Three Weeks</td>
</tr>
<tr>
<td></td>
<td>Sask. Council For Crippled Children and Adults</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physiotherapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Orthopaedics</td>
<td></td>
</tr>
<tr>
<td>Pathology</td>
<td>Chemical Pathology</td>
<td>Three Weeks</td>
</tr>
<tr>
<td></td>
<td>Hematology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Histology</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular Surgery</td>
<td>Operating Room</td>
<td>Five Weeks</td>
</tr>
<tr>
<td>Hospital Maintenance</td>
<td>Mechanical Shop</td>
<td>Four Weeks</td>
</tr>
<tr>
<td></td>
<td>Dietetics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>House-keeping</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Electronics Shop</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Security</td>
<td></td>
</tr>
</tbody>
</table>
### III. HEALTH CARE FACILITIES VISITED DURING INTERNSHIP

<table>
<thead>
<tr>
<th>HEALTH CARE CENTER</th>
<th>LOCATION</th>
<th>% OF ROTATION TIME SPENT HERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sask. Aids to Independent Living</td>
<td>Saskatoon</td>
<td>0.51 %</td>
</tr>
<tr>
<td>Childrens Rehab. Center</td>
<td>Saskatoon</td>
<td>1.5 %</td>
</tr>
<tr>
<td>Sask. Council for Crippled Children and Adults</td>
<td>Saskatoon</td>
<td>2.6 %</td>
</tr>
<tr>
<td>Wascana Health Center (long term patient care facility)</td>
<td>Regina</td>
<td>0.51 %</td>
</tr>
<tr>
<td>Pasqua Hospital</td>
<td>Regina</td>
<td>2.1 %</td>
</tr>
<tr>
<td>General Hospital</td>
<td>Regina</td>
<td>5.0 %</td>
</tr>
<tr>
<td>University Hospital</td>
<td>Saskatoon</td>
<td>87.17 %</td>
</tr>
</tbody>
</table>
III. THE ELEC DEVICE SUPPORT MATERIAL

BIOLGIC EFFECTS OF ELECTROMAGNETIC FIELDS

To the Editor: I take issue with Mr. Larrick’s statement, in the March 16 issue of the Journal, that “magnetic fields and radio-frequency energy utilized in NMR [nuclear magnetic resonance] are harmless.” Although earlier publications may have given such an impression, in the light of more recent work, indicating that biologic molecules and even cells are affected by strong magnetic fields, it is clear that further research is necessary before spectrometry using nuclear magnetic resonances becomes acceptable clinically.

AC magnetic fields above 100 G (varying at 10 to 100 Hz) evoke a visual response, “the magnetophosphene,” in the retina. A preliminary study in man showed that a 1-G (45 Hz) magnetic field has a slight but statistically significant effect on cognitive skill assessed by the Wilkinson Addition test and Response Analysis tests. The United States Navy’s proposed project Sanguine (also known as Sealarker), a system designed to permit communications with submerged nuclear submarines, has led to a close look at the possible harmful effects of electromagnetic radiations on human and lower forms of life. However, these experiments showing mitotic delay in slime molds deal with magnetic fields of 60 to 75 Hz at levels of 2 G, which are quite low, as compared to the 1000-G fields necessary for whole-body NMR with nuclear magnetic resonance spectrometry. A Soviet survey of industrial workers relates pathological changes in the hands and cardiovascular system to magnetic fields of moderate strength (hundreds of gauss at the hands and somewhat less at the trunk). Constant magnetic fields are reported to slow wound healing by a delay in fibrosis and fibroblast production. Though the number of subjects was small, one study indicates that serum levels of triglycerides are elevated a day or two after exposure to a magnetic field of 1 G (45 Hz). Furthermore, electromagnetic fields, whether external natural or man-made, tend to accelerate circadian rhythms. All of which goes to show that though the spectromatograph of a lemon on the cover of Nature (December 23/29, 1977) does not necessarily portend that the new imaging technic is a lemon itself, it is premature to suggest that computerized axial tomography scanning is on its way out. Just when scanning installations are approaching the ability to meet clinical demand, such a statement, given undue credence, may unfairly affect administrative purchasing decisions. It will remain to be proved that magnetic fields and radion energy used in whole-body spectrometry with nuclear magnetic resonance are less hazardous than the ionizing radiations used for imaging now available.

The quote from this article used by sales personnel of the Elec company is, “magnetic fields and radiofrequency are harmless.”
V. REPORT ON THE EXTERNAL HEART PACEMAKER FOR TESTING BUNDLE OF HIS

6.1 ABSTRACT

The following is a report submitted to Dr. J.F. Lopez by K. Magee (Clinical Engineering intern). It describes the front panel wiring of a W.P.I. pulse generator, necessary to give two desired pulse trains. Also included are theories of operations for both set-ups. Additionally, a couple of suggestions are given which are intended to increase the reliability of the generator as a whole.

6.2 OBJECT

To determine the connections for the W.P.I. pulse generator to produce a desired pulse train (Figure 1). As these pulses will be used to simulate arrhythmias of the human heart, it is desirable to have as much similarity between the simulated and actual arrhythmia waveforms. Two different pulse trains are desired to be produced.

1. A number of normal pulses terminated by a single Premature Contraction (P.C.). This P.C. is then followed by the the long silent period normally seen in a "compensatory cycle".

2. A train of normal pulses followed by a series of P.C.'s. Again, the premature contractions are followed by a period of time during which no pulses occur.

It was found that the first of these two pulse trains could be easily generated. The second could also be easily produced it is hypothesized, aided by a relatively simple circuit.
6.3 PART 1: A Single P.C. Followed by a Dead Space

This pulse train was fairly easily generated using the front panel hook-up for the W.P.I. as shown in Figure 2. The theory of operation for the set up is as follows.

In the above diagram the rates of the controlled stimuli (s1) are generated in the Model 830 INTERVAL GENERATOR (set on INTERNAL MODE) and are picked up by the Model 832 PRESET CONTROL via its SYNC INPUT. The number of pulses set at PRESET N are then routed via the N OUTPUT to Pulse Module #1 through EXTERNAL INPUT.

Module #1 is set to zero DELAY and passes pulses, which are set to a 2 millisecond WIDTH, to a Module 850A photon-coupled battery operated isolator and on to the subject.
At the end of a preset number (8 pulses here) the Preset Control is triggered by the trailing edge of pulse #8 and initiates a 1/N pulse which is cabled to Module #2 through EXTERNAL INPUT. Module #2 delays the pulse for the set 60 milliseconds and then sends a pulse of 2 milliseconds width (premature stimulus s2).

Module #3, set to be triggered by the trailing edge of this pulse, passes a pulse (s3) of 2 milliseconds after a delay of 600 milliseconds. Pulses from channels 2 and 3 are both routed through Module 850A Stimulus Isolator Module to the subject.

The sequence of events may be triggered externally by a signal such as a cardiac event or internally by the Interval Generator. Pulse settings may be programmed for a delay of 0 to 99 seconds and widths of 10 microseconds to 99 seconds. An LT (long time) system is available which increases the settings by a factor of 10. This system may be expanded up to 8 channels.

6.4 PART 2: A Series Of P.C.'s

The second stimulus pulse waveform, that shown in Figure 1b, was found not to be produceable with the equipment provided. It was determined however that with a relatively simple electronic circuit, shown in Figure 3, the desired waveform could be able to be obtained.

The theory of operation here is basically the same as was the case for the above waveform. The change that does occur here is
with respect to module 1. Here, the pulse used to trigger the premature contractions, from the "1/N" port of the 832 module, is fed to the designed circuit of Figure 4. This pulse is used to tell the circuit to couple a string of P.C.'s to module 1. The number of P.C.'s is determined by the setting of dial A of Figure 4 (RI Figure 3). Module 1 uses these pulses as trigger pulses to produce the P.C.'s. Therefore, the characteristics of the premature pulse are determined by the settings on module 1. The designed range of P.C. frequencies is 200 bpm (0.5 s), to the limit set by module 1. Then by adding 0.5 s to the setting of the delay dial of module 1, any pulse frequency within these limits can be obtained. As mentioned, the pulse width of the P.C. is determined by the setting of the width control of module 1.

6.5 NOTE:

During the initial trial of the W.P.I. unit to generate the pulse train of part 1, it was discovered that no output pulse from the machine was generated when the output was connected to the patient. This was determined to be due to the deterioration of the "Dry Cells" power supply of the W.P.I. generator. This particular problem was found to be undetectable during the operation as the monitoring of the output pulse could not be easily done. Therefore the loading of the output could not be seen when connected to the patient.

Due to the above described incident then, it is strongly suggested that some permanent means of checking the loading
effect on the generator be implemented. A couple of suggested means of doing this are as shown in Figure 5. It is desirable to have such a monitoring device permanently affixed to the generator for the following reason. During an operation, if the doctor is unable to immediately obtain the desired effects, understandably he immediately begins to question the equipment. If the above mentioned device is available he can immediately check the output of the generator. Also, when two or more complex pieces of equipment are present, it alleviates some frustration on the part of the doctor if he knows for sure which pieces of equipment are working.

An additional suggestion for bettering the reliability of this piece of equipment is the changing of the "Isolator" power supply from dry cell, which at present is difficult to obtain from the manufacturer, to rechargeable nickle cadmium cells. This suggestion is at present being implemented by Mr. T. Jackson and the Electronics Department.
PULSE TRAIL

-- A --

C

-- B --

D

E

F

EQUIPMENT

830

831

831A

831

832

830A

Typical Values

A - 2 ms
B - 2 ms
C - 600 ms
D - 200 ms
E - 1200 ms
F - 6 events
**Figure 3: Proposed Circuit To Give Multiple PC's Out**

- From U1 Port of 832
- Q Output

**NB:** Sitter May appear if very high PC rates are desired.
Figure 4. Proposed System for Part 2.
Figure 5: Suggested Power Supply Monitoring Devices

Connected to output of 850 Isolator

Nominal Internal Resistance (500Ω)

100 kΩ

10 μF

1 mA meter movement

Fuses IF Power Supplies Are Maintaining Voltage Under Load.
VI. REPORT ON THE H/P 1533A E.C.G. DATA COLLECTION SYSTEM

6.6 Introduction

The following is a report submitted to Dr. J. F. Lopez by K. Magee (Clinical Engineering Intern) concerning the H/P 1533A E.C.G. data collection system. This is a system which permits transmission of electrocardiograms from some remote area in the hospital, and there may be several, to a central location for analysis and storage.

The advantage the system has over the existing method used to transport the data to the lab, is that the technician does not have to carry all the traces back to the lab with her at the end of the day. Therefore it reduces the possibility of misplacing the traces when transporting them to the lab. A further feature of the system is that the transmitted electrocardiograms are individually identified by a patient identification number and accompanied by patient history data (Figure 1). Hence the system also allows for less of a chance of confusion developing over the identification of the E.C.G.s.

Concerning the investigation this paper reports on then, the reason it was undertaken was to solve two problems. These are:

1. Upon introduction to the system, it was found that data could not be transmitted from the remote 351A Data Transmitter to the 1533A E.C.G. acquisition system. It was desired by the head of the Cardiology Department that the reason for this be discovered.

2. At the initial acquaintance of the system it was believed that "cross talk" could be heard on the line.
NOTE: Illustration shows standard 12-lead recording on 50 mm channel width paper using fine-line stylus.

Figure 1: Sample print out from a 12 lead E.C.G. on the H/P 1533A Collection System
Since the lines used were supposed to be "dedicated", it was strongly desired to know if such undesirable interference was present.

In addition to reviewing the above points, this report also indicates some undesirable aspects encountered during the investigation. Also, suggestions as to how these factors may be remedied are given.

6.7 Discussion

This system consists of basically two sections. These are a receiving and a transmitting section. These two parts are connected, as mentioned above, by a normal telephone line. For the system investigated, there were seen to exist three dedicated telephone lines for this purpose. A block diagram for this set-up is shown in Figure 2.

Of the two problems the student was to investigate, it was felt that the first was the most important. Hence the student undertook to find the system fault first. Following the same logic depicted in Figure 2, the analysis of the overall system was broken into two portions, the transmitting end and the receiving end. The methods available to the student to carry out the investigation were the same for the both sections. That is, due to the status of the student and certain other prohibitive factors, an in depth and conclusive study could not be made into the operation of the H/P system. These factors can be quickly listed as.
Figure 2: Simplified block diagram for H/P 1533A E.C.G. Collection System
1. Being a student and not the company service representative, the authority to do a technical "bench" analysis of each component of the system was not present. Thus only a general suggestion as to the location of the fault can be given.

2. Due to provincial laws, unauthorized tampering with telephone company (Saskatchewan Telephone Company) installed devices is illegal. This problem was foremost when attempting to analyze the Telephone Line Coupler (Figure 4).

3. The student had to be concerned with not interfering with the normal operation of the E.C.G. Lab and the associated transmitting sites.

4. It was found that documentation on the instrumentation used by the H/P E.C.G. Collection system was not available.

5. The amount of time that could be allotted to this investigation was prohibitive towards an in depth analysis of the problem.

Fully realizing the limitations the above factors posed, the student proceeded to attempt a location of the above mentioned system fault. Because of the above factors, the type of tests that could be carried out were also limited. In essence, the investigation performed was some what of a "blind testing" technique consisting of the following points.

1. Review the manufacturers literature about each section of the H/P system.

2. Consult the staff of the E.C.G. lab about the problems with the system that they have encountered.

3. Ensure the integrity of the three dedicated lines. This was done by consulting with the Engineering and Maintenance Department, who were in charge of overseeing the installation of these lines.

4. Attempt data transmission from two different transmitting sites in the hospital.
5. Do a manufacturers suggested visual inspection of the receiver.

6. Make working diagrams of where the fault may be located. Then attempt to verify these with test results.

With the test procedure as listed above, the student proceeded to investigate the H/P 1533a Collection System. This investigation began with an evaluation of the Transmitter and transmitting sites.

6.7.1 The Transmitting Site

For the H/P E.C.G. Collection System, the instrument used to transmit the data is visualized through Figure 3. The three sections depicted were found to be included in one mobile unit. In the University Hospital then, there existed three such mobile units. To facilitate the limited number of these devices, and since each unit could be easily transported to different areas of the hospital, in the transmission sites in the hospital could be found data ports for transmitting the data to the lab. This was done by having a "patch cord" connect the transmitting unit to a wall plug, thus allowing access to the dedicated phone lines. The list below shows the different sites in the hospital from which E.C.G. signals could be transmitted with this system.

<table>
<thead>
<tr>
<th>Transmitter Zones</th>
<th>Location</th>
<th>Distance to receiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Care</td>
<td>Third Floor</td>
<td>500-1000 Feet</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>Third Floor</td>
<td>500-1000 Feet</td>
</tr>
<tr>
<td>Pre-School</td>
<td>Third Floor</td>
<td>500-1000 Feet</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>Third Floor</td>
<td>500-1000 Feet</td>
</tr>
</tbody>
</table>
The transmitter unit as shown by Figure 3 consists of a regular E.C.G. pickup amplifier and monitor, with the capability of outputing a twelve lead E.C.G. recording to a hard copier (a strip chart recorder). The signal is also seen to be routed through an encoder. This is seen to be used to modulate the signal as well as append the keyed in patient data in preparation for transmission. The third component of the transmitter is the automatic dialler and phone line coupler. This device permits access to the receiver through the telephone line.

As a test for this end of the system, it was repeatedly attempted to transmit data from different sites within the hospital. It was determined that in the automatic mode, the instrument accesses the receiver in the following manner.

First, of course, the technician makes the standard twelve lead connection to the patients chest, and ensures that a good clean
Figure 3: Block diagram for E.C.C. mobile transmitter unit.
E.C.G. signal is obtained (the signal is displayed on a C.R.T. on the mobile unit). She then enters the patient identification number and history data on a keyboard located on the unit. The phone transmitter then dials the telephone number of the Collection System receiver. This number is noted to be held in permanent memory on the mobile transmitter unit. When the call is answered, the phone transmitter records the patient's electrocardiogram (on the electrocardiogram chart recorder) and transmits all the E.C.G. data to the Collection system's memory location.

Provided with each of the mobile transmitter units is a two-way telephone receiver. This permits two-way communication between the technician and the Lab. Therefore, the technician is able to manually dial the system receiver, as well as listen down the line when the automatic dialler is trying to access the receiver. It was when the student was listening on the hand-held receiver during one of these attempted transmissions that he identified what was originally thought to be "cross talk" on the line. It is now understood that the automatic dialler transmits the phone number as a string of tones. It was this string of tones that was erroneously thought to be the cross talk.

As the investigation progressed, it was found that the transmitter was still unable to communicate with the receiver. It was observed that a clean E.C.G. was being obtained, and therefore was thought to be conditioned as specified by the
manufacturer. It is pointed out here that if the electrode leads, even one of the twelve, became detached before the signal could be transmitted, no data would be transmitted until the lead was re-connected. The only possibility of the fault existing with the transmitter then is if it were in the automatic dialler, or the phone line coupling circuitry. However, as mentioned earlier, the automatic dialler could be heard sending dial tones down the line in the attempt to connect with the receiver.

Due to the above two observations that the E.C.G. was being cleanly picked up and that the auto dialler was attempting to dial the receiver, for the time being, the transmitter was ruled out as the location of the fault. Concentration was therefore shifted to the receiving end of the system.

6.7.2 The receiver

The receiving end of the H/P 1533A Collection System was seen to be located in the E.C.G. Lab of the hospital in which this investigation was carried out. As shown in Figure 4, the receiver can be comprised of several different components. For the system investigated, the modules present were observed to be:

1. An EDC 1001A phone line coupler, used to answer and terminate telephone calls upon command. Since there were three incoming lines for this system, three such phone line couplers were seen to be employed.

2. An H/P 5615F multiplexer, used to access one of the three lines upon command. This was done by scanning the three lines until an incoming call was detected. The multiplexer would then lock on that line until a cessation of the call occurred.
Figure 4: H/P 1533A Collection System, showing major components of Receiver
3. An E.C.G. Receiver/Controller. This module received the frequency modulated data at its' input. It then demodulates the data into a 0-100 Hz. analog signal, and the appended identification information. The analog data is supplied to a system A-D converter for processing.

4. The output storage medium. This could be a magnetic tape, strip chart recorder, or a second computer.

The tests that could be performed on the receiver were mostly observation. For the multiplexer, the manufacturer had built in a row of three lamps, one for each of the incoming telephone lines, which lit as the device scanned the three input lines. This therefore was the first thing that was checked.

It was observed that the manufacturer specified actions were tacking place with the scan lights of the multiplexer. Therefore, it was decided, that the fault must be somewhere before the multiplexer, nominating either the telephone lines or the phone line coupler. The lines however had already been guaranteed to be as specified for dedicated data transmission. The logical site of the fault, if it existed in the receiver, would be in the EDC 1001 phone line coupler.

As mentioned, each of the three dedicated lines used by the system were terminated at the receiving end by an EDC 1001A. Each of these modules had its own control switches (mounted on the outside of the case). At the time of the investigation it was observed that the setting of these switches corresponded for two of the three modules only. On the third, one of the switch positions was different from the position of the corresponding
switch on the other two couplers. The control switches for the three controllers were shifted so that the same switches were in the same positions. As will be pointed out later, transmission of data was now possible, indicating that this may be the location of the fault. If this was the fault, a more qualitative analysis of it would be desired. However, this is not possible due to the total absence of any literature on the device, as well as the lack of sufficient time to search out the information.

The investigation had thus far narrowed down the areas of possible faults to two alternatives. These were that either the Automatic Dialler was not operating properly, or else the phone line coupler was not set right. Due to the peculiarity in the switch settings, the second possibility was immediately suspect. Therefore, after adjusting the control settings on the Phone Line Coupler, the system was tested to see if could now transmit data. This test was performed using both the Auto Dialler option as well as the manual dialing method of establishing the link.

The result of the above test was that a connection with the receiver and the subsequent data transmission could be made with or without the control switch of the Phone Line Coupler adjusted. This however was only true when the manual dial option was employed. When using the Auto Dialler, no connection or transmission could be made except when the above mentioned adjustment was made. Therefore, a re-evaluation of the transmitter was required.
Stated previously, the Auto Dialler could be heard to dial the receiver. With only one number placed in memory with which it is to dial the receiver, it will continue to dial this number until the connection is made. If, however, the Phone Line Coupler is not set so as to permit answering, no such connection will be made. This is what is felt to be the circumstances surrounding the Auto Dialler tested.

The aspect of having one specific number stored in the transmitter memory could explain on other inconsistency observed about the operation of the system by the staff. It was learned that at certain times a data transmission had been accomplished. This was even with the settings of the controller as described above. It is hypothesized that the numbers put in the Auto Dialler by the manufacturer were different. Therefore, each of the transmitters would attempt to access a different Phone Line Coupler. Therefore, depending on the transmitter with which transmission was attempted, the system configuration, as found at the outset of this investigation, would appear to operate inconsistently. Such was the case described by the staff. Because of the seemingly erratic behavior of the staff, skepticism towards the merits of the system was also evident.

From this final part of the investigation, further problems associated with the system were seen. These were mostly the reluctance on the part of the E.C.G. technicians to use the transmitter capabilities of the 351A Transmitter at all. Rather,
they preferred to rely wholly on hard copies obtained at the transmitter sites. This is the exact factor the system is supposed to eliminate however. The cause for for the reluctance to use the transmitter can be attributed to three main factors:

1. Foremost, it was discovered that the E.C.C. technicians were never given proper instruction on the operation of the 351A Transmitter. This would tend to indicate that they were considered to have their Electronics Technologist or Electrical Engineering degree and could determine the workings of these devices themselves. This however is definitely not the case. The real problem that this creates is that the technicians may not be fully aware of the capabilities of the device, which could eliminate some of their current problems.

2. Due to the problem of not being able to make the data link to the 1533A, or having to wait a long time for the connection to be made, the technicians have become skeptical about the reliability of the Transmitter.

3. Finally, it was observed that a significant amount of time was required by the technician to program the patient data. This delay was further lengthened if an error was made in the programming, or if one of the electrodes became disconnected. Understandably then, the technician did not like using the transmitter because of the time factor involved, especially if the patient load was heavy. This problem may have been produced by the factor mentioned in part one.

From the above described investigation, it was seen that without further in depth trouble shooting, aided by proper documentation, the system fault cannot be clearly identified. However, two possible areas where the problem may lie have been identified. These were noted and are listed at the back of this report. Additionally, the above paragraphs point out some very undesirable aspects of the maintaining and operating of the system. Some possible remedies for these are also listed at the
back of this report.

The above discussion concludes the findings on the investigation into the inoperative status of the IS33A E.C.G. Collection System. The second problem, that of the possibility of "cross talk" on the telephone lines has also been felt to be conclusively solved. To reiterate, it was decided that the dial tone of the Transmitter was mistaken for this cross talk. It is therefore concluded that the dedicated lines are operating as desired and causing no problems to the systems' operation. This observation concurs with the statements made by the Engineering and Maintenance department personnel.

6.8 IS33A system areas of possible fault

1. Setting of the control switches on the EDC 1001A Data Coupler. The result of this problem would be that one or possibly two channels could not operate.

2. The automatic dialer on the 351A Transmitter may not be sending a strong enough signal to trigger the switching circuitry on the telephone line. This is felt to be highly improbable however, with respect to the location of the fault, as the ringing of the phone could consistently be heard across the phone line.

3. Intermittent problems with the Auto-Dialer may have resulted in the intended receiver number not being the number that was actually transmitted. This would have resulted in no data link connection being made. This area is suspect as, on several test transmissions, the Telephone Operator indication was that the number dialed was not in service.

4. It was felt that with the different Auto-Dialers being programmed with different receiver numbers, and unless the same Transmitter was used for all attempted transmissions, inconsistencies in the operation of the system may be suspected. The problem was seen to be generated if, on the first attempt, the receiver
number was to the EDC 1001A Coupler that is suspected
as being off, and then on the second attempt was with
a Transmitter programmed with a different Receiver
number.

5. Finally, the ever suspected operator error may have
caused the fault. Due to the fact that care was taken
to ensure that the proper operator and set-up
conditions existed during the tests, the fault is
believed to be located else where.

As indicated above, it is felt that the fault was in the
transmission portion of the system (1533A E.C.G. Acquisition
System). Specifically, the most probable location is believed to
be with the control setting on the Phone Line Coupler. The
possibility still exist though that the fault lies with the
Auto-Dialer, on the 351A Transmitter. This is at least felt to be
an area that generates some skepticism on the part of the staff
toward the system. Reasons for these observations are documented
within the associated report.

Also, as pointed out in the above mentioned report, is the fact
that the exact location of the fault could not be determined.
This was due to two main reasons: nonexistent documentation, and
insufficient time to do an in depth trouble-shooting session on
the system.

Finally, the report indicates that no fault was found, or is
presently suspected, with respect to the dedicated telephone
lines.

6.9 Methods of increasing laboratory efficiency with respect to
high technology equipment
1. Ensure that proper training is given to the Laboratory Technicians (L.T.), on every new piece of high technology equipment that enters the department. This could be either having a manufacturers representative come to the hospital to give instruction, or send some of the Technicians away for courses on the device. At the very least, one person in the department should have sufficient knowledge on the operation of the device.

2. Make sure that all possible documentation on all department equipment is obtained and kept in a single place (for example, in a file cabinet in the department). This documentation would include the manufacturers material, as well as notes and course material the Technicians obtain during their learning experiences on the individual devices.

3. Ideally, a singular technically inclined person, for example an electronic Technician or Engineer, should become familiar with the intended departmental operation of the devices. This enables him to better understand breakdown descriptions as given him by the L.T., and hence decrease repair time.

4. Attempt to purchase equipment affording maximal "in-house" repairing. This is as opposed to relying totally on manufacturer service contracts.

5. Try to have the hospital Electronics Department perform regular preventative maintenance checks on all the equipment within the department.

The above points indicate that smooth operation of such a facility as the E.C.G. Lab. requires input from many different sources. These include: (1) the Doctor, (2) the Laboratory Technicians, and (3) the hospital Electronics Department or staff Clinical Engineer.
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